



Journal of the Association of Food and Drug Officials

Serving the regulatory community since January 1937

Contents of this Issue

	<u>Page</u>
From the Executive Director	1
2016-2017 AFDO Board of Directors	2
2016-2017 AFDO Board-Appointed Advisors.....	2
2016-2017 AFDO Committee Chairpersons	3
AFDO Regional Affiliates	5
2016 AFDO Award Recipients	6
2016 AFDO Resolutions	7
About the Authors	11
President’s Address.....	17
Glenn W. Kilpatrick Address.....	21
U.S. Food and Drug Administration Associate Commissioner for Regulatory Affairs Update	26
Change of Leadership in the FDA’s Food & Veterinary Medicine Program	37
USDA Food Safety Policy Changes	40
FDA’s Quality Agreement V. Ema’s cGMP Chapter 7 Outsourcing	48
Effective Writing Sets You Apart in the Health Care Field: A How-To Guide	56
Summary of Retail Food Inspection Scoring, Grading, or Placarding Systems ..	63
From the AFDO Archives (1997)	74
Co-Relation Of Sate Pharmacy Acts With State Drug Laws”	74
Coordination Of Federal And State Project Plans State Participation	78

From the Executive Director

Expect Great Things

Few can deny that the Food Safety Modernization Act (FSMA) and efforts to integrate the national food safety system have created an intense environment of “changing times.” Everywhere one looks, they can see the transformations that are beginning to challenge the foundations of our food safety society.

In this climate of dynamic change, the organizations that will succeed will be those that invest in adaptability and evolve beyond their core product or service.

AFDO believes that shared knowledge is shared strength, and we are committed to passing on resources of information and inspiration to all sectors of the food, drug, medical device, and cosmetic communities.

AFDO has always been an organization of great vision dating back to our creation in 1896. While we can be proud of our history, we must be prepared for our future and recognize the need to make investments for tomorrow. A look at the efforts that AFDO will do this year are more than promising – they are inclusive of regulatory officials that have traditionally not been part of the AFDO family. They are, however, part of the communities we represent including the Integrated Food Safety System (IFSS) which has become our principal endeavor in recent years. Here is a look at just a few of the things you can expect from your organization this year:

- An increase of funding to nearly \$1.9 million in awards provided to state and local retail regulatory agencies to improve their retail food protection programs
- Funding in the amount of \$675,000 in awards provided to state shellfish and dairy regulatory agencies to improve their dairy or shellfish safety programs
- Conducting webinars on the health, safety, and quality related to cannabis & cannabis related products for all interested AFDO members
- Providing training funds of up to \$1.8 million to assure state officials receive training in the Food Safety Preventative Control Alliance (FSPCA) program.
- A stronger outreach to government and industry officials in the drug, medical device, and cosmetic communities

We will also have our sights set on reaching the \$1,000,000 goal set by George Burdett for the AFDO Endowment Foundation years ago. So many AFDO members have longed for this, and we so badly wish to meet this goal this year. That would be great – but that’s what we expect from AFDO!

Enjoy your AFDO Journal



Joseph Corby
AFDO Executive Director

2016-2017 AFDO Board of Directors

<i>President</i> * [∇]	Steven Mandernach
<i>President-Elect</i> * [∇]	Pamela Miles
<i>Vice-President</i> * [∇]	Steven Moris
<i>Secretary/Treasurer</i> * [∇]	Natalie Adan
<i>Past-President</i> *	Stan Stromberg
<i>Executive Director</i> *	Joseph Corby
<i>Association Manager</i> *	Krystal Reed
<i>Director-at-Large</i> * [∇]	Benjamin Miller
<i>Director-at-Large</i> [∇]	Brenda Morris
<i>FDA Advisor</i>	Barbara Cassens
<i>USDA Advisor</i>	Keith Payne
<i>DHS Advisor</i>	John Martin
<i>CDC Advisor</i>	Vince Radke
<i>Health Canada Advisor</i>	Kenneth Moore
<i>CFIA Advisor</i>	Nicole Bouchard-Steeves
<i>AFDOSS Regional Affiliate Director</i> [∇]	Mark Sestak
<i>CASA Regional Affiliate Director</i> [∇]	Erik Bungo
<i>MCAFDO Regional Affiliate Director</i> [∇]	Elizabeth Nutt
<i>NCAFDO Regional Affiliate Director</i> [∇]	Katherine Simon
<i>NEFDOA Regional Affiliate Director</i> * [∇]	Darby Greco
<i>WAFDO Regional Affiliate Director</i> [∇]	Randy Treadwell

* *Member of Executive Committee*

[∇] *Voting Board Member*

2016-2017 AFDO Board-Appointed Advisors

- Cynthia Culmo, Abbott Laboratories
- Gerald Wojtala, International Food Protection Training Institute
- Doug Saunders, The Coca-Cola Company
- Nancy Singer, The Compliance-Alliance, LLC

2016-2017 AFDO Committee Chairpersons

Administration Committee

*Jessica Badour** (404) 656-3627
Georgia Department of Agriculture
19 Martin Luther King Jr. Dr. SW, Atlanta, GA 30334

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

Alumni Committee

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

Nancy Singer (703) 525-9581
nancy@compliance-alliance.com

Drugs, Devices & Cosmetics Committee

*John Misock** (240) 402-1423
US Food and Drug Administration
john.misock@fda.hhs.gov

Dennis Baker (214) 316-0037
(Retired) FDA Regional Food and Drug Director
dbakerjr@cebridge.net

Food Committee

*Jim 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

Erik Bungo (804) 786-3520
VA Dept. of Agriculture & Consumer Svcs.
erik.bungo@vdacs.virginia.gov

Food Protection & Defense Committee

*Jennifer Pierquet** (515) 577-3003
Iowa Dept. of Inspections and Appeals
jennifer.pierquet@dia.iowa.gov

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

Foodborne Outbreak & Emergency Response Committee

*Alida Sorenson** (651) 201-6025
Minnesota Department of Agriculture
Alida.sorenson@state.mn.us

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

Brenda Holman (240) 402-1676
US Food and Drug Administration
brenda.holman@fda.hhs.gov

Industry Associate Membership Committee

*Doug Saunders** (404) 676-5229
The Coca-Cola Company
Ricsaunders@coca-cola.com

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

International & Gov't. Relations Committee

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

Ken Moore (416) 973-1452
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

Richelle Richter (425) 487-5301
US Food and Drug Administration
daniel.rice@fda.hhs.gov

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

Dan Rice (425) 487-5301
US Food and Drug Administration
daniel.rice@fda.hhs.gov

Laws & Regulations Committee

*Matt Colson** (850) 245-5544
FL Dept. of Agriculture and Consumer Svcs.
Matthew.colson@freshfromflorida.com

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

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

Shana Davis (859) 619-0640
Kroger
Shana.davis@kroger.com

Retail Committee

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

Joseph Graham (360) 236-3305
Washington Department of Health
Joe.graham@doh.wa.gov

Kimberly Stryker (907) 269-7628
Alaska Dept. of Environmental Conservation
Kimberly.stryker@alaska.gov

Craig Nielsen (404) 656-3627
Georgia Department of Agriculture
Craig.nielsen@agr.georgia.gov

Elizabeth Nutt (918) 595-4301
Tulsa Health Department
eanutt@tulsa-health.org

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

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..... **Erin Sawyer**
New York State Department of Agriculture & Markets
(518) 457-5380
Erin.sawyer@agriculture.ny.gov

Mid-Continental Association of Food and Drug Officials

MCAFDO President..... **Melva Ball**
Nebraska Department of Agriculture
(402) 471-6814
Melva.ball@nebraska.gov

North Central Association of Food and Drug Officials

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

North East Food and Drug Officials Association

NEFDOA President..... **Elisabeth Wirsing**
Vermont Department of Health
(802) 951-0109
Elisabeth.wirsing@state.vt.us

Western Association of Food and Drug Officials

WAFDO President..... **Sarah Robbin**
Cascade City-County Health Department
(406) 761-9883
srobbin@cascadecountymt.gov

2016 AFDO Award Recipients

The **Harvey W. Wiley Award** is AFDO's most prestigious award. This year's recipient, **Richard Barnes**, was honored for his outstanding service and devotion to the administration of food, drug and consumer protection laws of our country. Mr. Barnes was the Director, FDA's Division of Federal-State Relations, from 1995 until his retirement in 2010. He initiated the development of "eSAF" (electronic state access to FACTS) to capture state contract data. He was the driving force behind the development and implementation of the 50 state meeting, the 50 state conference calls, and the Manufactured Food Regulatory Program Standards (MFRPS).

The **Associate Member Award** was presented to **Julie Larsen**, is a Principal Consultant and Director of Inspection Readiness Services at BioTeknica, Inc., a quality and regulatory compliance and engineering consulting firm in Coral Gables, Florida. Julie is a Certified Quality Manager (CQM), a Medical Technologist (MTASCP) and has more than 25 years' experience in quality assurance and compliance in the medical device and pharmaceutical industries.

The 2016 **Achievement Award** was presented to **Sarah Good**, Technical Specialist with the Virginia Department of Agriculture and Consumer Services. 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:

Genesis Casco, University of Southern California, PhD in Genetics

Joshua R. Smith, Colorado State University, B.S. in Biomedical/Mechanical Engineering

Molly Smith, University of Georgia, B.S. in Environmental Health Science

2016 AFDO Resolutions

RESOLUTION NUMBER 2016-01

Submitted by: AFDO Board of Directors

Date: June 24, 2016

Concerning: FDA's Use of Private Laboratories

Whereas, FDA is using and plans to use private laboratories for a variety of analytical purposes including regulatory purposes, and

Whereas, AFDO believes the use of non-governmental private laboratories for governmental regulatory work may have an adverse effect on public trust and consumer confidence including the possibility for conflicts of interests, and

Whereas, the absence of standardization or certification of non-governmental private laboratories could result in legal questions concerning government regulatory actions and product recalls on U.S. food companies, and

Whereas, AFDO fully supports the use of appropriately standardized Food Emergency Response Network (FERN) laboratories and other state laboratories that have achieved ISO/IEC 17025 accreditation for purposes of increasing capacity, and

Whereas, state laboratories play a critical role in food protection as envisioned in a nationally integrated food safety system, and

Whereas, the Food Safety Modernization Act (FSMA) only authorizes establishment of third party certification for foreign third party laboratories and programs, therefore be it

Resolved, that AFDO requests FDA to explore appropriate authority to establish basic criteria for domestic third party laboratories so that appropriate standards are established as they are with state food laboratories, and

Be it further resolved, that AFDO recommends that FDA first utilize state FERN laboratories or other state laboratories that have achieved ISO/IEC 17025 accreditation for any domestic regulatory food testing when needed.

RESOLUTION NUMBER 2016-02

Submitted by: AFDO Board of Directors

Date: June 24, 2016

Concerning: Costs for Analytical Samples

Whereas, AFDO strongly supports a nationally integrated food safety system that utilizes the available resources of state and local government levels, and

Whereas, state and local governments have illustrated their support for a nationally integrated food safety system, in part, by having their food testing laboratories meet accreditation standards, and

Whereas, to be successful, a nationally integrated food safety system must include a willingness of all government partners to share analytical data from a robust surveillance system that includes environmental and finished product testing, and

Whereas, the cost of collecting and analyzing environmental and finished products can inhibit state and local agencies from doing this sampling, and

Whereas, state food safety programs will be relied upon by FDA to assist them in meeting the mandates of the Food Safety Modernization Act (FSMA), therefore be it

Resolved, that AFDO request FDA to consider possible funding mechanisms to state and local government food laboratories that perform environmental or finished product testing relating to the surveillance of food, and be it further

Resolved, that AFDO request FDA to work with them in developing work plans to assure state and local food laboratories are properly utilized to assure adequate coverage of food commodities

RESOLUTION NUMBER 2016-03

Submitted by: AFDO Board of Directors

Date: June 24, 2016

Concerning: Decrease in FDA Contract Inspections for States

Whereas, FDA and the states have a long tradition of working closely together through formalized contracts, partnerships, and cooperative agreements, and

Whereas, these efforts have had a positive effect on addressing the workload challenges of FDA while providing funding to states to assist them in building infrastructure and standardized programs, and

Whereas, during FY2015 states performed 9,365 FDA contract inspections accounting for 56% of the total number of inspections reported by FDA, and

Whereas, states must maintain FDA inspection contracts in order to meet Manufactured Food Regulatory Program standards, and

Whereas, passage of the Food Safety Modernization Act (FSMA) will result in the creation of more inspection work to be conducted, and

Whereas, FDA has publicly stated it is interested in shifting more domestic inspections to the states allowing FDA to devote more of their attention to international work, and

Whereas, it is unclear whether FDA intends to hire more field inspectors to do domestic inspections, and

Whereas, states are reporting that some FDA Districts have significantly decreased contract inspections to states at a time when workload is increasing, therefore be it

Resolved, that AFDO request FDA to clarify, as specifically as possible, its policy position on state contract inspections as it relates to joint work planning and leveraging of state resources, and

Be it further Resolved, that AFDO advises FDA of the need for better coordination, consistency, guidance, and monitoring of work planning between FDA Districts and states to ensure efficient use of limited resources, and maintain adequate inspection coverage and public health protection.

RESOLUTION NUMBER 2016-04

Submitted by: AFDO Food Committee

Date: June 24, 2016

Concerning: Marijuana Infused Edibles

Whereas, health risks associated with marijuana infused edibles have been thrust into the national spotlight, and

Whereas, studies have suggested an association between marijuana infused edibles and psychological disturbances, and

Whereas, the potential risks associated with the rapid consumption of marijuana infused edibles can be compounded by its delayed effects, and

Whereas, consuming multiple servings of marijuana infused edibles, especially at one sitting, has an additive effect for potential psychological effects, with the possibility for over sedation that can lead to paradoxical or unusual reactions that can trigger intense anxiety, paranoia, or even frank psychosis, and

Whereas, the safety of marijuana infused edibles can be compromised by potential adulteration with other illicit substances or drugs of abuse, and

Whereas, AFDO recognizes the importance of reinforcing the need for packaging and labeling rules that edibles contain no more than 10 mg of THC and have clear demarcation of each 10 mg serving, and

Whereas, CDC clearly recognizes the danger of marijuana edibles by suggesting, “a need for improved public health messaging to reduce the risk for overconsumption of THC”, and

Whereas, the history of food and drug law illustrates the critical need for federal oversight through technical assistance to the states, guidance to manufacturers, information to consumers, and, where necessary, national legislation, therefore be it

Resolved, that AFDO request FDA to clarify, as specifically as possible, its policy position on marijuana infused edibles, and

Be it further Resolved, that AFDO advises FDA of the need for federal leadership on the matter of marijuana infused edibles and for providing guidance and technical assistance to the states on appropriate regulatory intervention in order to avoid the creation of a patchwork of state regulations covering this issue.

About the Authors

John Avallanet, is the founder of Cerulean Associates LLC. He served as the industry expert reviewer for the international standard, BSI 10008 Evidential Weight and Legal Admissibility of Electronic Information (2015). In 2014, he co-authored the book, *Pharmaceutical Regulatory Inspections*, with several current and former regulatory agency officers, and his industry classic, *Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine* (2010), was originally featured at BIO 2011. He has served on behalf of the US Department of Justice overseeing a multimillion dollar consent decree and was the lead author of several certification courses for the US Regulatory Affairs Professional Society.

Barbara Cassens, is the Director for the Office of Partnerships within FDA's Office of Regulatory Affairs. She has held this position as the acting director since February 2013, and as the permanent position since 2016. Her office supports enhanced investments in federal-state-local collaboration, integration and manufactured human and animal food standards. Ms. Cassens has been with the U.S. Food and Drug Administration since 1990 starting as a field investigator and then assuming the roles of marine biotoxin coordinator, dairy specialist, Pacific Region Cooperative Programs Director and San Francisco District Director. Her past work has included a number of federal-state integration projects such as joint work planning and development of the first federal-state food emergency response team, CALFERT. She also leads a Food Safety Modernization Act (FSMA) team in implementation of inspection and compliance portions of the rule. In 2010, she was lead of a multi-disciplinary FDA team for designing new approaches to inspections and compliance within the foods program. Prior to joining the federal government, Ms. Cassens worked as a food technologist and program manager in research and development/quality assurance for Nestle, Dole Packaged Foods, and John Labatt Limited. She holds a Bachelors of Science Degree, Food Science Curriculum, from Iowa State University. Ms. Cassens is former president of the Western Association of Food and Drug Officials and is active in the parent organization, AFDO, as well as being a member of the Institute of Food Technologists and the International Association for Food Protection.

Amy Chang, For the last several years, I have successfully worked on several federally funded cooperative agreements applying my skills in project planning, coordination, and promotion to food safety environmental health service projects. I have been responsible for balancing multiple priorities while working with local health departments to support their efforts around food safety and environmental health services. I have served as a key personnel working on the FDA-NACCHO Cooperative Agreement, "Strengthen and Promote the Role of Local Health Departments in Retail Food Safety Regulation" for over four years. Some of my numerous responsibilities for the cooperative agreement have included coordinating, planning, and providing technical assistance for the Mentorship Program for the Retail Program Standards, connecting public health accreditation to the FDA Retail Program Standards, and conducting case studies on retail food establishment scoring, grading, and placarding systems.

Also in my current position as Program Analyst for NACCHO, I am responsible for tracking current Food Safety issues and policies. I synthesize research findings and then draft and/or revise materials based on findings. I routinely communicate with local health department staff via e-mail, distribution lists, and the NACCHO Web site regarding requests for information, funding opportunities, conferences, training opportunities and other information. I have coordinated and hosted webinars venues on project specific topics. I continue to represent NACCHO through presentations to promote projects at meetings and conferences.

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. Daniela Drago, is an Assistant Professor and the Program Director of Regulatory Affairs for George Washington University's School of Medicine and Health Sciences. She has extensive experience in global regulatory affairs encompassing the US, Europe, Asia Pacific and Latin America. Prior to joining academia, she worked in the pharmaceutical and medical device industry for companies ranging in size from start-ups to Fortune 500. Her experience includes regulatory compliance, strategy and writing. Dr. Drago has written and reviewed a number of global regulatory submissions, participated in numerous meetings with regulatory agencies, and provided strategic regulatory advice. During her tenure in industry, Dr. Drago trained regulatory, quality and sales personnel.

Dr. Stephen Ostroff, served as FDA's Acting Commissioner until February 2016. Previously, he was FDA's Chief Scientist, where he was responsible for leading and coordinating FDA's cross-cutting scientific and public health efforts. The Office of the Chief Scientist works closely with FDA's product centers, providing strategic leadership and support for FDA's regulatory science and innovation initiatives.

Dr. Ostroff joined FDA in 2013 as Chief Medical Officer in the Center for Food Safety and Applied Nutrition and Senior Public Health Advisor to FDA's Office of Foods and Veterinary Medicine.

Prior to that, he served as Deputy Director of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention (CDC). He retired from the Commissioned Corps of the U.S. Public Health Service at the rank of Rear Admiral (Assistant Surgeon General).

Dr. Ostroff was the Director of the Bureau of Epidemiology and Acting Physician General for the Commonwealth of Pennsylvania and has consulted for the World Bank on public health projects in South Asia and Latin America.

Dr. Ostroff graduated from the University Of Pennsylvania School Of Medicine in 1981 and completed residencies in internal medicine at the University of Colorado Health Sciences Center and preventive medicine at CDC.

He is a fellow of the Infectious Disease Society of America and the American College of Physicians, and prior to assuming the role of FDA's Acting Commissioner, he chaired the Public Health Committee of the American Society for Microbiology's Public and Scientific Affairs Board.

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.

Jennifer Li, is the Senior Director for Environmental Health and Disability at the National Association of County and City Health Officials (NACCHO). She oversees environmental health projects, including climate change, environmental health practice, environmental public health tracking, health impact assessment, health in all policies, healthy community design/built environment, food safety and defense, vector control, water quality, health and disability, etc. She also has experience in chronic disease, informatics, and preparedness. She is primarily responsible for ensuring that environmental health and disability programs and services at the local level are enhanced through NACCHO's activities, sustaining an effective knowledge base of current environmental and health and disability programs, policies and priorities among practitioners, representing environmental health and disability issues and priorities within strategic planning discussions, providing leadership for long-term planning related to NACCHO's work, and working to secure sufficient resources for NACCHO's environmental health and disability activities.

During her tenure at NACCHO, she has represented the organization on the National Environmental Health Partnership Council, Environmental Public Health Coalition, and served on various committees, including Environmental Health Conference Planning Committee (Present), National Environmental Public Health Conference Planning Committee (2009), National Healthy Homes Conference Planning Committee (2010-2011), and Disability and Health Partners Meeting Planning Committee (2010-2011). Jennifer also became a scholar of the Mid-Atlantic Health Leadership Institute, sponsored by the Johns Hopkins Bloomberg School of Public Health (2006).

Jennifer obtained her Masters of Health Sciences from Johns Hopkins Bloomberg School of Public Health with a focus in Environmental Health Sciences. She also holds a Bachelor of Science from University of Michigan with a concentration in Natural Resources and Environmental Policy.

Carl Mayes, is currently the Assistant Administrator (AA) for the Office of Investigation, Enforcement and Audit (OIEA) in the Food Safety and Inspection Service (FSIS) at the

United States Department of Agriculture (USDA). He leads the Agency's surveillance and investigation activities for incidents of foodborne illness outbreaks, recalls, natural disasters and intentional contamination. Mr. Mayes also oversees state and foreign audit programs and enforcement and litigation functions for FSIS. Prior to joining FSIS, Mr. Mayes worked for the Defense Intelligence Agency (DIA), serving as the Mission Application Division Chief for Counterintelligence (CI) and Human Intelligence (HUMINT) software applications. Previously, Mr. Mayes spent 21 years in the United States Air Force (USAF), where the majority of his time was spent with the Security Forces and supporting Command, Control, Communications, Computers, Intelligence, Surveillance and Reconnaissance (C4ISR) activities.

Dr. Susan Mayne, is the director of the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA). In this position, Dr. Mayne leads the center's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, food and color additives, and cosmetics.

An internationally recognized public health leader and scientist, Dr. Mayne received a B.A. in chemistry from the University of Colorado. She earned a Ph.D. in nutritional sciences, with minors in biochemistry and toxicology, from Cornell University.

She comes to the FDA from Yale University, where she was the C.-E.A. Winslow Professor of Epidemiology. Her distinguished career there includes two leadership positions: chair of the Department of Chronic Disease Epidemiology and associate director of the Yale Cancer Center.

Dr. Mayne has conducted extensive research into the complex role of food, nutrition, and other health behaviors as determinants of chronic disease risk. She is author or coauthor of more than 200 scientific publications.

She recently completed two consecutive terms on the Food and Nutrition Board of the National Academy of Sciences, and a five-year term on the Board of Scientific Counselors for the U.S. National Cancer Institute. She also served on a nutrition advisory committee for the FDA. She has worked closely with other government agencies, including the U.S. Department of Agriculture, on developing practical applications of research.

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.

Nancy Singer, founded Compliance-Alliance LLC in 2004 to specialize in the professional development for FDA and industry staff. Previously she served as the Special Counsel for the Advanced Medical Technology Association. Nancy received Vice President Gore's Reinventing Government Hammer Award and the FDA Commissioner's Special Citation. She began her career as an attorney with the United States Department of Justice doing litigation for FDA enforcement cases. Subsequently, she was a partner at the law firm of Kleinfeld Kaplan and Becker. Nancy is on the faculty of George Washington University Medical School and Health Sciences and is a retired commander in the Naval Reserve.

Stan Stromberg, is currently employed by the Oklahoma Department of Agriculture, Food, and Forestry, where he is the Food Safety Division Director. He received a B.S. in Animal Science from the University of Arizona. Following graduation he was employed by a national meat packing company for 13 years, where he worked in sales, product management and plant management. He was self-employed for three years in the food manufacturing business. He has been employed by the Oklahoma Department of Agriculture, Food and Forestry in a regulatory capacity for over 29 years. He began his career with the Oklahoma Department of Agriculture, Food, and Forestry as a meat inspector. He progressed to a meat inspector supervisor, the meat inspection program coordinator, the Director of the Meat and Poultry Inspection Program, and the Director of the Food Safety Division. In his current position he has overall responsibility for the dairy inspection program, the egg inspection program, the egg, poultry and red meat grading program, the meat inspection program and the organic certification program.

He served as a member of the USDA National Advisory Committee on Meat and Poultry Inspection for two terms of two years each. He is also the past president of the National Association of State Meat and Food Inspection Directors and is currently the president of the Association of Food and Drug Officials. He is also the PFP Training and Certification Work Group co-chair.

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
Stan Stromberg
Oklahoma Department of Agriculture, Food and Forestry
AFDO 120th Annual Educational Conference
Pittsburgh, PA – Sunday, June 26, 2016

It is a great honor for me to be standing here this evening speaking to you as the AFDO president. When I was preparing this presentation, I thought back to the first AFDO Annual Educational Conference I attended in 2008 in Anaheim, CA. The president was Steve Steingart with the Allegheny County Health Department, the president-elect was Jerry Wojtala with the Michigan Department of Agriculture and the vice-president was Ron Klein with the Alaska Department of Environmental Conservation. Are any of those names familiar? My introduction to AFDO was a little unusual. Ralph Stafko was the USDA advisor to the AFDO Board at the time. Ralph was also the FSIS liaison to the State Meat and Poultry Inspection Programs. I was the vice-president of the National Association of State Meat and Food Inspection Directors then. Ralph contacted me and asked if I would be interested in attending the AFDO Conference if all my expenses were covered. I agreed and then he said "Oh, by the way, you will be the chair of the Meat and Poultry Committee". I have not missed an AFDO Annual Educational Conference since. I believe that AFDO is an exceptional organization whose members are dedicated food and drug safety professionals who are interested in helping each other ensure a safer food and drug supply. It is very satisfying that I have been able to be a part of this group and have been able to contribute to the organization. It is my hope that someone who is here today as a first-time attendee will someday be standing up here as the AFDO President.

This last year has been a whirlwind of activity for me. It is hard for me to believe that a year has passed since I assumed the AFDO presidency at the close of the Annual Educational Conference in Indianapolis. I had the pleasure this last year of attending all 6 of AFDO's affiliate meetings starting with last year's conference in Indianapolis that was hosted by NCAFD. This was followed by the AFDOSS Conference in Gatlinburg, TN, the WAFDO Conference in Helena, MT, the MCAFDO Conference in Branson, MO, the CASA 100th Annual Conference in King of Prussia, PA, and the NEFDCA Conference in Saratoga Springs, NY. In addition, I represented AFDO at a number of other meetings around the country, including the Seafood HACCP Alliance Meeting in Baltimore, the FSIS Office of Outreach Employee Education and Training (OOEET) All Hands Meeting in Washington, the FDA Training Summit in Rockville, MD and the Food Safety Summit in Chicago.

During this last year we have seen huge changes detailed in the FDA FSMA Final Rules that will have a major impact on the future food production landscape. Not only are we going to take a new approach to the regulatory process for food products, we are soon going to be regulating fruit and vegetable farming operations that many of us have never done before. This began last September when the "Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventive Controls for Food for Animals" and the "Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventive Controls for Human Food" Final Rules were published. In November, the "Food Supplier Verification Programs for Importers of Food for Humans and Animals"; the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"; and the "Accredited Third-Party Certification" Final Rules were published. In April of this year

the “Sanitary Transportation of Human and Animal Food” Final Rule was published. And in May, the “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration” Final Rule was published. These six Final Rules did not leave many stones unturned in the food production world.

Since 1998, AFDO has been calling for the creation of a nationally integrated food safety system. In order to successfully implement these six FSMA Final Rules, all of us that are involved will need to redouble our efforts in this arena. We have all seen great strides made to attain this goal. The efforts undertaken and the progress that has been made by the FDA’s Partnership for Food Protection and its committees have been phenomenal. Many AFDO members have served in important roles on the PFP and its committees since its inception. When you hear the reports of the successes that have occurred in states that have Rapid Response Teams where different agencies worked cooperatively on an investigation and in situations where agencies that were not a member of a Rapid Response Team, but they still worked together in a cooperative manner with other agencies, with each party bringing their own expertise and skill sets to the table which resulted in a more effective investigation, you realize that we are making progress. In spite of all these advances, we still have not attained the goal of a nationally integrated food safety system.

To continue to make progress towards the goal of a nationally integrated food safety system, many of us are going to need to make some changes that may be uncomfortable for us. Many of you have heard me talk before about the need to eliminate turf claims, to get out of our silos, and open lines of communication with our partner agencies. At this point I want to stress the importance of the concept that communication is a two-way process. Unfortunately some people believe that communication is when they speak and the other person listens and is not allowed to provide feedback or their feedback is disregarded. This is not communication, it is dictation. Two-way communication is the key to the development of a mutual trust between agencies and the personnel who work within them. Listening is a critical component of communication. If the mutual trust is not developed where agencies and personnel within them are willing to share data or feel that they can rely on the accuracy of the data they receive from another agency to make informed, supportable decisions we will never be able to reach our goal of a nationally integrated food safety system. I encourage each of you to make a personal commitment to advance efforts for the attainment of a nationally integrated food safety system.

I would like to highlight some of AFDO’s achievements this last year.

- AFDO continues to have monthly conference calls with FDA’s Office of Partnership where we have frank conversations about issues that need to be addressed or resolved.
- AFDO continues to play a major role in the Seafood HACCP Alliance
- The Directory of State and Local Officials has been updated to include state dairy contacts, state shellfish contacts, and the FSIS Directory of Meat, Poultry and Egg Products Establishments
- Three new guidance documents are being developed for shared kitchens, wild mushrooms and allergen control at retail
- AFDO is offering \$1,700/Affiliate for future leaders to attend the AFDO Annual Educational Conference

- AFDO will fund one person per Affiliate to attend the Train the Trainer courses for Preventive Controls and Produce Safety
- Voluntary National Retail Food Regulatory Program Standards Grant
 - Total number of awards Made: 350
 - 294 local jurisdictions
 - 53 state jurisdictions
 - 3 tribal jurisdictions
 - Total amount of funding awarded: \$1,975,363
- Manufactured Food Regulatory Program Alliance Meeting was held in Louisville, KY, February 1 – 4, 2016
- AFDO presented an Integration Forum at the Food Safety Summit in Chicago on May 8, 2016 that was both well attended and well received.
- Grants and Cooperative Agreements that are being managed by AFDO:
 - Alliance for Advancing a National Integrated Food Safety system
 - Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed
 - Designing a Voluntary National Retail Food Regulatory Program Standards in Support of a National Integrated Food Safety System
 - Food Code Tracking Contract
 - NASDA Produce Safety Implementation
- AFDO is continuing to meet with FDA to discuss initiatives and innovative methods to enhance training delivery capacity.

I would like to thank all the AFDO staff, Krystal, Randy, Patty, Pat and Jessy for all the help they have provided to me this last year. Anytime I needed anything they were all quick to make it happen. I also want to recognize Joe Corby for his advice and guidance during this period. In addition the AFDO Officers, Board Members, Advisors, and Committee Chairs have gone out of their way to be helpful in any way they could. I can't leave out my wife, Susan who has always been supportive of my involvement in AFDO. She was the one who was home alone when I had to travel. Finally, I would like to thank my agency, the Oklahoma Department of Agriculture, Food, and Forestry and Mr. Jim Reese, the Oklahoma Secretary of Agriculture who has been very supportive of my participation in AFDO.

AFDO's Vision Statement is; "Promoting Public Health, Fostering Uniformity, and Establishing Partnerships". AFDO's mission is to successfully foster uniformity in the adoption and enforcement of science-based food, drug, medical devices, cosmetics and product safety laws, rules, and regulations. Please keep these two statements in mind during this meeting and then take them home with you when you return to your job. I would also encourage you to become active in one of AFDO's many committees, many of the activities or initiatives that our organization undertakes began in an AFDO Committee. I would also urge those of you who can devote the time, to consider running for an elected office. The strength of AFDO is built on the commitment and efforts of its members. I can tell you from personal experience that I have gained a tremendous sense of accomplishment and satisfaction by being associated with and being able to contribute to such an outstanding organization.

I will repeat what Steve Stich said in his closing last year because he said it so well. “It has been an extreme honor and privilege to serve you, AFDO’s members, and represent this fine association as President.”

Thank you.

###

Glenn W. Kilpatrick Address

Barbara Cassens

**Director, Office of Partnerships, Office of Regulatory Affairs, FDA
Character, Commitment and Community
AFDO 120th Annual Educational Conference
Pittsburgh, PA – June 26, 2016**

When Steve Stich called to offer this speaking opportunity to me, I was extremely humbled to be asked to give the Glenn W. Kilpatrick Memorial Address and the opportunity to honor such a noteworthy leader and man of vision. You see, I remember when I first joined FDA in 1990. I was coming from ten years working in the food industry, in research and development, and really did not know much about AFDO. My first AFDO Annual Educational Conference was in 1991. As I sat in the audience that afternoon, like some of you here now, I listened to Tom Messenger, Director, Colorado Department of Health, give this address. I thought to myself, wow, he must be a very important person in this organization to be chosen to honor Mr. Kilpatrick at such an important occasion. I had no earthly idea at the time that I would be standing in front of you today, giving this address. It is an exceptional honor and truly a highlight of my public health career.

Reflecting back on Mr. Glenn Kilpatrick, I did some research into his life, what he experienced, and thought about what might have made him tick. As I speak today, I will focus some of my comments directly to Mr. Kilpatrick. Now, if he should answer me this afternoon... well, that will definitely make this an address that you all might well remember in the years to come!

Glenn Kilpatrick embodied the attributes of those who grew up during the difficult 1930s. He later served in the armed forces of the 1940s, specifically as a pilot in the Army Air Corps where he received several prestigious military awards. Glenn was one of those special people that Tom Brokaw referred to as the "Greatest Generation." I can personally relate to this as my father lived through these times. He worked and struggled during the depression and later served over 4 years in the army before coming home with the rank of sergeant. This experience of my youth has enabled me to relate to the strength and character of Glenn Kilpatrick.

Glenn's insight into the strength of all agencies; federal, state, international and local, working in concert, hold even truer today. Glenn understood that even when we are doing our job individually we are still working together. If we could ask Glenn how he accomplished the extraordinary things he did, I believe he would not refer to himself as being extraordinary. I believe he saw himself as an ordinary person doing his job the best that he could.

Glenn joined the FDA in 1970 from his position of the Director of Food and Drugs in Utah. Let's all reflect a moment as to where each of us was in 1970...and I know there are some of you in this audience who were not yet even born. Personally, in 1970 I was in sixth grade and planned to be a veterinarian. It would not be until a decade later that I would enter the work force as a food scientist. As each of you reflects on your career, I would believe you would agree there have been changes you could not have

foreseen or imagined, and those events took you on a road not expected, but offered new opportunities.

Glenn came to FDA, Division of Federal-State Relations (now known as Office of Partnerships) with an extraordinary vision of advancing states role in public health and enhancing integration at all levels. He championed the NRTSN communication system for real time communication from FDA to state and local public health partners. Today we use email, web posting and 50 state calls to do much of the same and we have improved our two-way communication and collaboration with forums such as the MFRPS Alliance. In many ways I hope that, in my current role, I am carrying on his legacy.

Now let's think about from where we have come since 1970:

- We have a law, FSMA (Food Safety Modernization Act), passed in 2011, that mandates integration of public health regulatory programs;
- The local, state, territorial and tribal public health partners have invested their talents and energy in adopting program standards (retail, manufactured human and animal food), a robust quality systems program, so that confidence in their public health program is shared across jurisdictions; and we rely on a community of associations to help FDA assess and enhance these standards;
- Our state regulatory partners currently conducted 60% of the human food inspections and 80% of the animal food inspections on behalf of FDA this past year;
- We have advanced the Partnership for Food Protection (PFP) and their seven work groups through increasing the breadth of membership, in both the workgroups and governing council, and establishing a six-year strategic plan to guide our collective integration efforts;
- Office of Partnerships alone has increase our investments in our partners from \$25 million dollars in 2009 to \$100 million dollars in 2016; with additional increases anticipated in 2017; and our ORA sister organization, DHRD, has invested multi-millions of dollars toward training of our public health partners alone and collectively with FDA staff;
- This year we are investing in over \$19M to support many state/territorial public health agencies in order to help implement the produce safety rule; this is the largest single cooperative agreement in the history of FDA Office of Regulatory Affairs (ORA), collaborating with NASDA, ASTHO and AFDO;
- Eighteen federal-state rapid response teams (RRT) are funded across the country that have proven to be not only a significant investment in joint emergency response and capacity building at all levels, but in increased collaboration through relationship building and mutual understanding;

- We have increased investments in laboratory sciences at the state and local levels to enhance food emergency response, support lab accreditation, two-way data exchange and build a laboratory network of support across the United States;
- We have enhanced support to, and visibility of, our three state cooperative programs (milk, retail, shellfish) which provide a level of public health protection impossible for FDA to do alone; and
- Most recently, we launched three mutual reliance pilots which will help inform the practices, policies and further investments needed to advance integration.

These examples are only to name a few.

So let me share with you three key things I learned about the man, Glenn W. Kilpatrick, related to a) Character; b) Personal Commitment; and Community.

Character

Glenn, many remember you as a great orator; someone who could “wax poetically” about state and local engagement in an integrated system. In a 1992 interview with Robert A. Tucker, Director of State Program Coordination Branch, in FDA Division of Federal-State Relations, he commented and I quote “Glenn was an eternal extrovert, optimist and marvelous impromptu speaker. We used to have a lot of planning sessions where Glenn would lead extensive discussions. As one of the grunts, I used to think, well, Glenn, this is great, but we’re going to use all our time up talking about this before we get down to getting the work done. But we always, somehow got it done anyway and with the benefit of a strategy that Glenn had developed.” Glenn, you had the confidence and poise to express your thoughts with clarity and utmost conviction. But it wasn’t just when you addressed an audience at the podium that your gift to clearly communicate was shown; it was in the day-to-day personal interactions with others. You knew what to say to inspire others to reach their personal best.

Personal Commitment

Glenn, you demonstrated your personal commitment to advancing public health early on through the way you brought a passion to the work place. You were not discouraged by professional set-backs and actually used such events to springboard to new ideas. In 1970, when you joined FDA, there were a limited number of state investments, mostly contracts focused on doing thing one way. Now we recognize that different approaches can achieve a similar public health outcome and that these approaches are not only acceptable but beneficial. We also have learned that through investing in foundational pieces, such as program standards and ISO accreditation, we build confidence in each other’s work. I hope you are impressed that today we have hundreds of state programs and local jurisdictions enrolled in program standards and have invested millions of dollars over the last eight years alone to support contract work, lab accreditation and federal-state initiatives. And for you, that personal commitment to excellence extended beyond your job; it was part of your family and community life. Which leads me to community...

Community

Glenn, you are remembered for saying “what about the states?” Your goal was to keep state needs front and center while advancing federal-state relations across the country. You championed greater involvement by FDA with associations such as AFDO. But you also had a strong respect for community and how only through working together in the spirit of organizations such as AFDO and its affiliates we could reach our public health goals. As we gather here tonight to kick off the 120th AFDO Annual Educational Conference, help us all – state, local, territorial, tribal, international and federal public health entities; industry and academia remember that working together hand-in-hand makes us successful in reaching the goals of an integrated food and medical products safety system.

May we all bring that spirit of strong character, personal commitment and celebration of community to our day-to-day lives.

As I have said more than once, we are on a journey to an integrated food and medical products safety system. And if we look back over our shoulder, the road has been long with twists and turns including resource surpluses and deficits, and a few set-backs along the way. Yet when we look ahead, we can see great leaders like Glenn W. Kilpatrick urging us to stay true to the course. We have enjoyed the successes and weathered the set-backs. We know there will be rainy days, when things aren’t always so bright; but because of the bridges and relationships we have built, and thanks to the activities fostered through associations such as AFDO, we know we can make it through together.

In closing, I want to share a picture with you all. (Slide) This is my father standing on our family farm in 1957, approximately four months before I was born. I keep this on my desk with a caption under it which reads “Two things you should never forget; where you are going, and from where you came.” As an optimist I believe Glenn Kilpatrick would have embraced that belief as well. And Glenn, I do believe you are watching us today and are proud for what you initiated decades ago.

Again, thank you for allowing me to honor Mr. Glenn W. Kilpatrick tonight, and thank you for your work every day toward an integrated public health system. Let’s enjoy another successful conference here in Pittsburgh and take the time this week to reflect on the vision Glenn imparted to us so many years ago.

I believe Glenn would be very okay by us finishing with the ending of Garrison Keillor’s Prairie Home Companion Show:

“Be well, Do good work, and Keep in touch”

Acknowledgements

My thanks to Brenda Stewart- Munoz, ORA Office of Partnerships, for her assistance researching the history of Glenn W. Kilpatrick working through the U.S. FDA History Office. While we did not meet our goal of finding a photo of Mr. Kilpatrick before the conference, we will continue the quest for AFDO’s historical files. I also want to

recognize my brother, John Cassens, an incredible orator, for his ideas and inspiration for this address and also his wife, Joan Cassens, a former English teacher, for her critical editing eye.

###

**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 120th Annual Educational Conference
Pittsburgh, PA – June 27, 2016**

(Transcribed)

Melinda Plaisier: Good morning everyone! I am really pleased to be here and with four of my colleagues- four new program executives in the Office of Regulatory Affairs: Alonza Cruse, director for Pharmaceutical Quality; Joann Givens, director for Human and Animal Food; Dr. Ginette Michaud, director for Biologics; and Jan Welch, director for Medical Devices and Radiological Health.

On behalf of FDA's Office of Regulatory Affairs, we are extremely grateful to have the opportunity to provide you with an update on the Office of Regulatory Affairs, and give you a little progress report on where things stand with our organizational and operational change efforts.

As many of you know, ORA is in the midst of the most significant organizational and operational change in the history of ORA. Change that is being driven by Program Alignment, an initiative started by our previous commissioner, which has been and continues to be supported and driven by FDA leadership to address the evolving public health challenges of the future.

We are preparing for major organizational changes; advancing fundamental changes in operations; continuing to implement legislation which has been at an unprecedented level, and investing in our own strategic priorities; including, investments in our workforce, process improvements, and developing new partnerships, while continuing to strengthen our existing partnerships.

The AFDO theme of "collaborating to strengthen food, drug and medical device safety systems" is consistent with ORA's focus this past couple of years as we collaborate internally and with our partners at the local, state, federal, global level and with partners in key associations, academia, and industry- all focused on strengthening our systems through change.

Let me briefly give you an update on the status of our realignment, and then I would like my colleagues to share an example of how the change we are implementing will strengthen our collaborations and our public health systems. Then, we want to leave time to take your questions and engage in a bit of dialogue with you.

You may recall under Program Alignment, some of the key changes include: establishing program based staffs and moving to exclusive specialization in one program for investigations, compliance and operational managers; moving away from a historical geographic management model to a program based management model for many

operational positions; establishing our 13 laboratories as a national science resource, reporting into the Office of Regulatory Science who will directly report to me. This effort predates Program Alignment, but will be an important step in elevating the visibility of regulatory science in ORA. Additionally, establishing four new import districts, totaling five, treating imports as its own area of specialization. With over 34 million line entries last year, and a historical 10% increase each year, we need an enhanced approach to import operations - organizationally and operationally.

We're going to pull our training division, the Division of Human Resource Development (DHRD) up and out of the Office of Resource Management and establish it as the Office of Training, Education and Development reporting directly to me. Training is critical to the future of ORA and our regulatory and public health partners, with or without Program Alignment. We have to continue to build training and education programs that are current, based on standards, measurable and sustainable. Bringing DHRD up to office status reflects the importance that training, education and development plays in ORA.

For state and local partnerships, we will establish our state cooperative programs as a national staff, consolidating all of our specialists by programs – such as a dairy staff, a shellfish staff and a retail staff, creating the Office of State Cooperative Programs within the Human and Animal Food Program. We'll retain our state liaisons, emergency response coordinators and other key partnership staff at the local or district level. These are some of the positions that really need to be retained based in geography.

We're establishing an integration staff in the Office of Partnerships to provide additional expertise and support to our collective efforts to advance our work within the Partnership for Food Protection as we work to affect an integrated food safety system and as we continue to implement FSMA. As you may have heard last night in the President's address, we have made a lot of progress toward an integrated food safety system but we're not there yet. We still have silos that need to be taken down and we need to be vigilant in practicing effective two-way communication and information sharing.

You also heard Barbara, in her eloquent Glenn Kilpatrick speech; briefly summarize our investments in our partnerships through contracts, grants and cooperative agreements. Our investments, as she noted, are at an unprecedented level. We are committed to both achieving an effective integrated public health system and to the partnerships that it is going to take for us to get there.

So these are just a few highlights of some of the key changes that Program Alignment will deliver. So where are we? We have been advancing alignment in two stages. First out of the gate was the lab realignment, followed by the larger ORA realignment. Both packages need commissioner approval, approval from the Secretary of HHS with congressional notification. The lab package has been signed by the Secretary, so that's an important first step. They're working on congressional notification and the larger (Program Alignment) package was signed by the Commissioner and is now at HHS.

Also, we are in the process of doing due diligence with our two labor unions, the National Treasury Employees Union and the American Federation of Government Employees. And lastly, even after we have all of the approvals and have completed our negotiations with our two labor unions, we also need to ensure that we have very clear and defined

transition plans that have been clearly communicated within ORA and with other stakeholders in order to launch the realignment.

There is an amazing amount of groundwork that has to be laid in order to effectively stand this up. Things ranging from delegations of authorities to basics like new accounting codes, time keeping measures, document management and a host of other critical operational activities that are going to be needed as well in our realignment. It remains my expectation and goal that we will have secured all of the approvals and completed our negotiations with our unions and be ready with our transition road map to be able to begin standing up in early Fiscal Year 2017. We'll certainly share with you news of our progress as we can.

I have to say getting us to this point has been a remarkable achievement by all of the men and women in ORA, particularly recognizing that change of any shape or scope produces anxiety and creates stress. It can be disruptive to operations and it is of course not embraced by everyone. I want to continue to commend ORA and to all of you ORAers sitting in here today, I want to thank you again, for stepping up and not only engaging and helping to define and lead the change but also ensuring that we did not skip a beat in carrying out our responsibilities to the agency and public health.

I said from the very beginning when Dr. Hamburg issued this charge in 2013 that 2014 and 2015 were going to be planning years. We took a lot of time to really try to do a thoughtful job of planning this. 2016 would be a transition year and our goal still remains that we will begin standing up in 2017. This truly is a transition year and the fact that I have four of our new program executives sitting up here with me today is a true reflection of the transition and the progress that we are making. We still have five acting regional food and drug directors who are leading the regions and managing day to day operations with our district directors while these program executives have really focused their attention on planning for the transition.

So let me just pause now and I'd like each of our executives to share with you an example of how some of this change effort is going to really yield a benefit and change for our stakeholders. So we'll just go down the line and then hopefully leave a little bit of time to engage in a bit of discussions. So Alonza, would you like to start?

Alonza Cruse: Good morning.

Participants: Good morning.

Alonza Cruse: I'd like to look at the important aspects of this Program Alignment initiative. It's the opportunity for us to really begin thinking differently about addressing challenges that we have had in the agency. And not necessarily challenges as a negative but challenges on looking to improve our individual processes and practices. So I'm just going to take a few moments to provide one of those examples and I think the rest of my colleagues here will do the same. I was told before I started that we have about four hours for this panel and I promise not to take more than hour.

So I'm going to talk about some of the team-based approaches that we're looking at doing in accomplishing our work in the Pharmaceutical Quality Program and we refer to it

internally as IQA or Integrated Quality Assessment. This team-based approach is helping us to align patient-focus with risk product quality issues in the making of recommendations for the new drug applications, the amended new drug applications, you know, those generic drugs and biologics license applications.

So historically, the various program centers would have their experts, their drug reviewers if you will, review the applications from sort of beginning to end. Under this new approach, we're bringing all of the disciplines together - microbiology, chemistry, biochemistry, pharmaceutical, biologics and inspections under one sort of team-based approach in the review of an application. We feel that integrating the review of the drug applications with the evaluation of the manufacturing facilities will lead to a single, more informed quality assessment not only of that site but of the quality of the application.

Somewhat different than what we're doing now. Right now, there's a review that goes on and then if there is an inspection needed or that inspectional assignment comes to ORA, we've got to conduct the assignment. We would not have known what was going on during the application review process. But this gives us sort of a unique perspective into that window.

It also will have the opportunity to provide the reviewer with the perspective from the investigator's perspective. The simplest question, "Have you considered this process in the review of that application?" But we've not because we didn't really know enough of that from the inspectional perspective; it really provides a different dynamic on the review of applications. This team-based approach we believe will have benefits for both the review and the inspection side in order because they'll lend their expertise to review of those applications.

Ultimately, what we want to achieve out of this is a timelier, more transparent, better communicated process. It will allow us to address issues that may come up, such as drug shortages, and this is an important end as we address parity from both the time we're doing inspections and review of our domestic sites versus our international sites. So we see it's a lot of benefits leading up to these team-based review practices.

This morning, Mel really did a good job in laying the groundwork for Program Alignment, and later on this morning, my colleague, Jan Welch, and I will be going through more details on the Pharmaceutical Quality and the Medical Products side about a specific activity we have going on within Program Alignment. So with that, I'm going to yield the microphone to my colleague to my left.

Joann Givens: Thank you Alonza and thank you Mel. Thank you AFDO for providing an opportunity to share with you some of the activities that we've been involved with from the Program Alignment perspective. And it's just wonderful to see so many great faces in the audience so hopefully during the break we'll get the chance to talk to you all.

I just wanted to share some of what we are doing as it relates to the Human and Animal Food Program. Now, when I was hired into this position it was called the Food and Feed program, but it's all one and the same.

So I want to spend some time this morning focusing on what we have been working on over time with regard to the national work plan. Some of you may be cringing in here because this is probably a pain point for many of our state partners. But I want us to look at a national work plan because I don't think that it's realistic to think that we would ever get to a national work plan but to view it as a national resource.

Resources on Program Alignment will be made available throughout the ORA organization. We are in the last year of our first cycle for FSMA high-risk and non-high-risk firm inspection frequency mandates. And, we are looking to handle the resources throughout the field organization along with our state partners. We're in this together. We're down to our last year for the non-high-risk inspection frequency mandate and this is a body of work that we must do collectively. In order to facilitate that, we are moving resources around from our current district structures to another district to help out where there may be some challenges in terms of getting that work or body of work completed.

One of the other things that Program Alignment affords us is to be strategic in our hiring. Hiring where the industries are, where the need is. It's no longer that cookie cutter approach but more importantly, focusing on the intelligence and the data which represents where the industries are. And to that end, it affords us that in a very constructive way.

Training will be focused to a specialized workforce. And that will lead to consistent decision making. We've been traveling throughout the country with regard to our FSMA implementation and we've heard from the industry, which may have firms on both coasts and same operation and different results in the way of how that inspection is conducted. Training of a specialized workforce will assist us in getting to consistent decision making and we think that's a significant advantage as it relates to Program Alignment.

And then we've been working very closely with the Office of Partnerships as well as the Partnership for Food Protection work planning work group. There have been a number of efforts in the last few years as it relates to work planning and how to get there, connecting all of the dots because at the end of the day, we need an accurate Official Establishment Inventory. We call it the OEI in order for us to allocate resources to the work at hand and to work plan efficiently and effectively with our state partners.

We recognize that there will be growing pains and we're experiencing growing pains as I sit here, but the ultimate goal is to standardize the process so that it looks the same no matter where you are and that's the direction that we're moving toward and I think Program Alignment affords us that.

But lastly, I wanted to convey that Program Alignment does provide us the flexibility to utilize skill sets wherever they are needed. And that's one of the major benefits of it because we can't train everyone in everything. But Program Alignment does allow us to focus our skill sets, our training and put those resources wherever they may be needed. And that's just a few of the highlights that are going on in the Human and Animal Food program. So at this time, I'll yield over to my colleague Jan Welch.

Jan Welch: Good morning everyone. Well, I'm very excited to be here. This is my first AFDO conference and I'm very excited to be part of this experience. And really, we were

only given five minutes to provide one example and perhaps answer one question. That was what we were tasked with.

So, it's important to me, that example that I'm going to talk about is related to radiological health. And I think it's important to note in the program name. It is the Medical Device and Radiological Health program. Often, it is just called the Medical Device program and it's not. It's very comprehensive. It's very thorough and trying to be very mindful of all the efforts that go into rad health.

So I want to talk a little bit about the nationalization of our Mammography Quality Program or the MQSA Program and work plan. Currently, our MQSA commitments and work planning occurs in our regional model that you know. You hear about and it works and coordinates with the states within that region. We have five very wonderful regional radiological health representatives and they currently work very, very collaboratively with each other and across the regions to ensure consistency in coverage, performance goals and succession planning. But they all operate in maybe a slightly different model and style. We are going to transition to a nationally aligned MQSA program, managed at the headquarters level and reporting in to me, the program director.

There would be dedicated MQSA inspection staff located throughout the country and their work and their assignments will be coordinated and monitored at the national level. So this is the question. "What will this do for you and what will this do for FDA? Kind of what's in it for us?" So I think what this is going to do is really provide more attention and focus and support on this important program to include goal setting and performance monitoring at the national level. I've been meeting frequently with these five regional rad health representatives and learning all about this. And I said, "Well, who coordinates and pays attention to what you're all doing in the five regions?" And there isn't really that national perspective, a national support and I really want to help do that for this program.

It will continue to provide continued specialization of the staff performing these inspections. These are very unique men and women; this is the only thing that they do. So currently, they could be pulled off to do some other work; such as in support of national emergencies, that's perfectly fine. But they shouldn't be pulled off to do other commodities and other work so this is really specialized and we need to support that. It will provide for more efficient pro-active planning around state contracts. I'm learning about these contracts. I learned that sometimes contracts go away due to financial constraints. If we know that the state has to drop its contract, well, we should be able to react a little bit more resilient to that. As well as you know, maybe there'll be new contracts again. It's not just always contracts going away; it might be an opportunity to gain some new contracts.

It will provide more agility to react to change throughout the fiscal year. It will allow for continuous optimized staffing and training including training to our state partners. So I'm learning about the very specialized training that goes on in this. And I think it's really going to ensure the focusing and clarity of the communication with our state partners and with the Center for Devices and Radiological Health. So that was that was my five minutes.

Ginette Michaud: Good morning. Can you hear me? Yes? Thank you very much for the opportunity to speak with you this morning. I am the director of the Biologics Program.

This is probably the program that you know the least about. And I am hoping in the next few minutes to tell you a little bit about our activities.

The Biologics Program is the smallest of the programs that are represented on this stage but it covers quite an array of different product types. These are by and large complex biological products and they all fall in to the definition either of a drug or a device. So in essence, our program covers vaccines and allergenic extracts, cell, tissue and gene therapies and certain devices related to their use, complex protein therapeutics like immunoglobulins, clotting proteins and their recombinant analogues, blood component, source plasma, the devices and drugs used in their collection, IVDs (In Vitro Diagnostic Devices) used for testing donors and recipients of these products and the final category is HIV test kits.

These products essentially correspond to the different product types that are regulated by the Center for Biologics Evaluation and Research (CBER). Consequently, the people who work in the biologics arena work quite closely with CBER. And ORA has had many years of collaboration with CBER in areas such as policy development and training activities.

Now, as I mentioned, the biological products are also devices or drugs. What that means is that they come under a number of different authorities, key of which are the Food, Drug and Cosmetic Act and the Public Health Service Act. From them flow many regulations, some for biological products, the regulations for devices, the regulations for drugs. So this is a rather complicated regulatory landscape and it means that specialization for the people working in the field allows them to focus more on those regulations and statutes that are relevant for the particular products that they work with.

We do believe strongly in this initiative of Program Alignment. It will increase the specialization of our workforce. This is something that's not entirely new in the biologics arena. We have a small team called Team Biologics that you may have heard of. This is a group of investigators and compliance officers that are uniquely focused on a subset of biological products such as vaccines and recombinant products and donor screening assays. And we found this to be a very successful program and it's essentially a model for expanding this specialization to our entire workforce, not only including the investigators - the front lines, but up the management chain so that we can have the depth of knowledge and training that is required across the board.

One thing that I want to mention before closing is that there is an overlap between the programs in the medical products arena and Alonza and Jan and I are very well aware of that. Think of the combination products, think of the fact that biological products are drugs or devices. There is a need and a recognized need for interaction between our programs to make sure that we are aligned across programs as appropriate and that we take similar and consistent approaches as needed. Those interactions have begun as we work to transition to standing up Program Alignment, and those communications will continue.

So in summary, the Biologics Program's specialization will enhance the ability of our workforce to keep paced with innovation and manufacturing processes in the industry. Thank you very much.

[Applause]

Melinda Plaisier: Thank you very much, colleagues. And I hope you heard - I know this was a very brief summary, but we really want to have a bit of a discussion with you. We believe Program Alignment is not only going to yield tremendous benefits to our own workforce through increased technical knowledge and expertise, increased career opportunity and really increased empowerment and decision making. Whether it's through a team-based approach or other approaches that we're taking about, there will be good results for you, our stakeholders, through consistent decision making and increased consistency in approach - standardization of processes. So, all around we think this is an incredibly important initiative that's going to really yield a lot of benefits for all of us and ultimately the main goal of public health.

So, we're happy to entertain some questions for any of us or comments - have a little bit of a discussion. Sure.

Participant: Hi, my name Anita Dalrymple. I'm with Biomerics in Salt Lake City where there are medical device manufacturers. And I'm very intrigued by the comment Alonza made about team application reviews. And I wonder if you thought through some of the logistics of how that might occur in a team setting?

Alonza Cruse: First of all, thank you for the question. Each one of those examples brings with it its own unique challenges in implementation. So what we have been doing now is the application review is primarily based out of our main campus. We are pulling in right now- we have been using program experts from our Office of Medical Products and Tobacco Operations within ORA as being that ORA conduit to it. As we move through creating a vertical integrative programmatically-aligned organization, we'll be able to further integrate the actual investigators into that individual team. Right now, we do have a little bit of a handicap because we're still operating in our current model

Again, the review is done out of headquarters. I attended, early on, a number of these meetings and we would be in a room and begin the discussion as a first step, the evolution of this program is to create a more communicative process by bringing in the appropriate experts to weigh in on the applications.

Participant: If I may just follow-up, is that true for medical devices as well? Are we seeing more of an integrated team approach to application reviews?

Jan Welch: No, I don't think so. Right now we're working on more of different post-market strategy where we're integrating both compliance staff from CDRH into the premarket process and where the ORA investigator and compliance officer come in, but not at the review level of 510K or PMA, hopefully we could keep that for the future.

Participant: Yes. Thank you.

Participant: Hi Mel, thanks for coming. Question for you and Joann, I think? Over the weekend there was a lot of discussion amongst the states about a lot of topics. One topic that kept coming up over and over again was the issue of work planning. Joann

and you guys are very familiar with it. States are working much more collaboratively with districts around work planning. They're very appreciative of that collaboration and negotiation. The question that keeps coming up though is around the mandated frequency of inspection. And if that's a floor or a ceiling? So, if you guys can clarify that that would be great.

Joann Givens: So, it is the floor, it's the minimum. And we have – in addition to our first cycle for our high-risk and non-high risk inspection frequency, what we have now included in that is the coverage. So, for us going out the gate, our high-risk, we really strive for meeting that in three years and now we're in the second cycle of the coverage. So embedded in the overall initial time frame, we now have to ensure that we are going back in there in a routine three or five-year cycle for those firms.

It does get a little challenging, I think I've mentioned growing pains, work planning because what we are learning through this process as, firms are required now to register, we recognizing that perhaps the inventory as we may have thought it to be is not what it is. In other words, we have firms that have registered but when we are working really closely with our state partners, in our clean-up efforts of the inventory, we don't have as many firms as perhaps we originally thought. So it does require a lot of collaboration and work planning and working closely with the states.

But this period where we are now is the growing pains and again, it's the floor - not the ceiling. It's the minimum. So if we want to inspect more frequently, we could. And again, we have messages even on the FSMA side that you know our scope of inspections will change so that means that if we are inspecting a particular area, the next inspection may be something else that we might want to focus on as we implement FSMA. So, just want to kind of clarify that hopefully that helps.

Participant: Yes, good morning. I'm Deborah Autor of Maryland. Welcome to Pittsburgh, my new hometown. Great panel, I'm especially impressed you guys could actually fit it in to the time allowed. So, I had a question for Alonza. You commented that the team-based assessment will help to contribute towards parity between domestic and foreign facilities. I was hoping you could elaborate a little bit more on how that will work.

Alonza Cruse: Thank you for the question. Parity has quite a few moving parts and paths that will help us get there. So as we are making the team assessments, we'll not only the drug review but we'll have sort of the ORA investigative perspective there. And if we do that, of course, the breath of the applications we're bringing, that voice out to be the similar perspective across the generic applications, the ANDAs, the NDAs, the BLA applications, a more uniformed approach.

Parity also comes with it - we're using one compliance program especially in surveillance programs as you may be familiar with addressing that. We're looking at the time it takes such as that we're spending on the actual inspection to make sure that we are applying the same rules. We began really looking into modeling and site selection modeling to help us run all the firms through that sort of one filter, if you will. If you could just imagine that is one effort to help us address parity issues. Parity brings to it multiple points along the chain and we hope that built together they bring that level of parity both foreign and domestic.

Participant: Thank you.

Participant: I've got a question for you. I used to do work planning at CFSAN and we thought our work was the most important work in the FDA. And years later, I talked to a district director who said he had blood banks to do, he had drug firms to inspect and foods probably weren't at the top of his priority list and I was wondering how Program Alignment is going to deal with all of the centers saying my stuff is more important?

Melinda Plaisier: I'll start and then each of our directors may want to add in a little. And I think one of the great things about Program Alignment, there are many great things but one in particular is the specializing of investigations, compliance and operational management into single programs, we can really manage that program's portfolio of work in a sort of more strategic and contained way if you will because we will know exactly what staff we have, exactly how many investigators, how many compliance officers, how many managers and thus really be able to manage - maybe as Joann says, not quite a national work plan but it is a goal that we have been talking about since Mike Chapell days.

Mike, I see you in the back of the room there and think about our past discussions of trying to rally across the programs and stop thinking about managing the work in geographic buckets and rather think about it nationally. It is really a global work plan - program by program. So I actually think it's going to be a benefit to our center colleagues by having, you know, having discreet staff and discreet leaders dedicated to managing that set of work. And we welcome any comments from any of you.

Joann Givens: It allows us to have full accountability for those who are responsible for the programs. So we're looking at that collectively as a group. The foods program, the pharmaceutical program and those individual leaders are going to be responsible. We are going to be responsible for ensuring that that program and the work is accomplished through the work plan process.

Participant: Steve Wietzman, having been around the agency for 45 years. This has got to be an immense undertaking, resource-wise and my concern is getting this information out to the public. And that's a big problem. Compliance policy guides are out of date, compliance program guides, out of date, staff manual guides are out of date. You got to get those things updated so people understand what this Program Alignment is really going to do. And that's got to require immense resources so who's working your budget?

Melinda Plaisier: I think of just a couple of comments you know, Program Alignment really is an agency initiative. Well, I know we in ORA feel like sometimes it's really all about ORA that we're the only ones really sort of slugging through this huge, huge change. But, the centers each have their own sets of responsibilities as well. And if you look at some of the alignment documents on the website, there was a February of 2014 document that we fondly called a decisions document. And it was where agency leaders came together after the charge and talked about it in terms of what are we going to agree to as an agency that we're going to drive forward under this umbrella of alignment?

And in that are what I sort of think are several pivotal areas. It's establishing the programs, its specialization, its imports, its labs, work planning but it's also compliance and enforcement. And that's where the centers really have the lead and ensuring that we have clear and current compliance policies and enforcement strategies. So, we have that over the last couple of years in our second round of action plans.

Action plans. So one of the other tasks that we were given was to establish with each program, with each center, an action plan. And so, last year, we had six action plans in ORA. They were all framed out more or less around those eight decision areas -- depending as each center's interest varied slightly, but that was really the framework for each. We had over 200 discreet action items in ORA that we were advancing across all of the programs. So, it is very much a shared activity. I think we're all in this together. We all and I mean, we, the corporate we, the agencies see the benefit that this is going to yield to operations to our workforce and ultimately as I said to public health.

So, to directly answer the question, there has been no increasing of the budget. We have in ORA started a new initiative -- yeah, one more thing to our list but it's an important one and that's -- capacity management. We are very actively working through our executive leaders, very actively working through how to really manage the capacity of what we have before us right now and going through an exercise of figuring out what you know, what has to be done immediately, what can we do maybe next year, what can we start parsing out on a more long term strategic phase. But we're all in.

Well, if there are no other questions. Just let me thank you very much again, on behalf of our entire team here, our new program executives. We really very much appreciate the opportunity to come and talk with you this morning and share a little bit about where things stand with Program Alignment. I want to thank you for your interest in ORA and most importantly, thank you for your continued partnership. It is going to take all of us if we are to ever achieve an effective and sustainable public health safety net. So, thank you very much and we look forward to the rest of the conference.

[Applause]

Pete Salsbury: Now, that's a great way to kick off a conference. So that's the first time I believe we've ever had all the leaders of the programs in ORA and the ACRA here at one time. So, thank you all for taking time out to come here today and being a part of this. For those of you who are in the drug and device sessions, Alonza and Jan will be giving presentations over there and I think Ginette will try to be over there. Take advantage of saying hi to Mel and Joann and the others while you're here.

Change of Leadership in the FDA's Food & Veterinary Medicine Program

Dr. Stephen Ostroff

**AFDO 121st Annual Educational Conference
Pittsburgh, PA – June 27, 2016**

Let me start my remarks by thanking AFDO for the opportunity to be here with you in Pittsburgh and for holding your annual meeting so close to home; at least to my home. I am from Pennsylvania and still live here, although I'm located a couple of hours to the east in Harrisburg, the state capitol, where I previously worked in the Pennsylvania Department of Health before joining the FDA.

I chose to live in Pennsylvania rather than relocating to Washington when I returned to Federal service because it allows me to stay closer to where the rubber meets the road at the state and local level, which is where most of you work. Even though I have now returned to working at a Federal agency, a part of me remains with you and I understand and appreciate the effort you make. If there is one message that I wanted to convey in this presentation, I think that was it.

While working at the Pennsylvania Department of Health, I served on the executive board and as President of the Council of State and Territorial Epidemiologists (CSTE) which is a sister organization to AFDO. So another message is that when you work at the state and local level, it is important and rewarding to get involved with your national organizations and contribute to the development of national policies. By coincidence, when I was President of CSTE, we held our annual meeting right here in Pittsburgh and the banquet was held in the very room where we're meeting today. So it's nice to be back in such a beautiful facility.

I have only been in the role of the Deputy Commissioner for Foods and Veterinary Medicine at FDA for a short time, taking over recently from Mike Taylor who was in the position for 7 years. [But even though my name tag says this is my first AFDO annual meeting, that is not accurate.] I attended and spoke at AFDO meetings while I worked at our sister agency the Centers for Disease Control and Prevention (CDC). I also attended and spoke at the CASA annual meeting while I worked at the health department here in Pennsylvania. That meeting was also held here in Pittsburgh.

Even though I've only been in the job a few weeks, I've already attended an AFDO meeting, a CSTE meeting, and a couple of National Association of State Departments of Agriculture (NASDA) meetings and I hope that I have the opportunity to do that more. As somebody who worked at the state level, I really do understand the critical importance of our local state tribal and federal partnerships and the important contributions you make to public health, food safety, and consumer confidence.

I hope that you feel that our partnership is a strong one and that it's a partnership in the truest sense of the word. Not on paper, not in words, but in actions and deeds. And if it's not, I want to know about it.

There are a number of examples that demonstrate the strength of our partnership. Look at the large contingent of people from FDA that are attending this meeting. They are not only from the Office of Foods and Veterinary Medicine that I lead, but also from the Office of Regulatory Affairs (ORA) and from other parts of the agency. The fact that you honored Barbara Cassens from ORA is a great example of the importance of our partnership.

We have strong programs with AFDO and AFDO members, including the Partnership for Food Protection, the Rapid Response Team (RRT) program, our work with state labs in testing capacity, and our work on the Food Safety Modernization Act (FSMA). These are only a couple of the notable examples. They all fall very clearly under the umbrella of the Integrated Food Safety System (IFSS) envisioned by AFDO. It's something that all of us at FDA strongly support.

The concept of IFSS is even more important now than it ever was, because FSMA is now moving from concept to reality with the finalization of the 7 foundational rules, the last of which was finalized on May 26th. It's an important 5-year milestone for FSMA, but it isn't the end. Instead, I refer to it as the end of the beginning. Because now comes the hard part - translating the words and concepts in the rules to reality on the ground.

We will need your help in doing that. We need your help to ensure that there are high levels of compliance by regulated industry with the content of those regulations. We need your help on education, training, and assisting regulated industries. And we need your help in telling us whether or not the rules are actually working the way we anticipated they should work. We need you to tell us what's going well and where are the problems.

We know the rules are very good because of the extensive public input we received in developing them. But they're not perfect. We've already identified some issues that we are addressing, but some might not become apparent until we are beyond the compliance dates. Therefore your feedback is important so that we can maximize the full benefits of FSMA to improve public health.

There's a lot of other work going on in OFVM besides the work related to FSMA. There's our nutrition work. We've recently had a string of successes in releasing regulatory updates and guidance's.

We just finalized the revisions to the nutrition facts label that includes a new line for added sugars to help consumers make informed choices about their diets and to address the obesity epidemic.

At the beginning of June, we published draft voluntary sodium reduction guidance, another measure that we think can really benefit public health. In May, the final guidance for complying with menu labeling requirements for listing calories on restaurant menus was issued. There are similar requirements for food items in vending machines.

It's a pretty remarkable list. There's also our work on addressing antimicrobial resistance, something that's close to my heart since I've worked on infectious diseases and public health for years. The reason finding of colistin resistance here in Pennsylvania demonstrates how important it is to address antimicrobial resistance. There is the issue

of GMO labeling with a law slated to take effect later this week in Vermont and impending Congressional action on labeling.

Another issue to mention is a recent alert issued by the HHS Inspector General that called into question the effectiveness of FDA's food recall process. Feedback of this nature is difficult. But I welcome the IG input because recalls are a critical component of our work on consumer protection, and it's an area we work on with AFDO and other state partners.

The IG focused on recalls that for one reason or another didn't quite go as smoothly or as quickly as they should or could have. It's unfortunate they did not equally focus on the thousands of recalls that went well during the period studied.

Where there are problems with recalls, we need to fix them. And we need to work with you to do that. I'm sure you will hear about some of the fixes over the course of the meeting so I'm not going to dwell on them now. We, in OFVM, will make these changes in partnership with ORA. There are several people attending the meeting that are involved in this effort.

Let me now touch upon ORA and the discussions that occurred earlier this morning. One of the keys to the success of FSMA implementation and other areas is the work that ORA is doing with respect to program alignment.

Program alignment is a fundamental paradigm shift within FDA and as you heard this morning, a fundamental shift in the way FDA works in the field and the way that we interface with you. It's the right thing to do and I want to publicly commend ORA personnel in the room that have been working so hard on program alignment and how far they've come in this effort. What a big difference it will make.

The last thing I just want to mention briefly is that we're about to issue our 10 year strategic plan for the OFVM that will cover the period 2016 to 2025. It's really intimidating to think that far into the future given how much our food supply and public health challenges are likely to change over that time period. Some examples are GMO, globalization, antimicrobial resistance, changes in manufacturing and technology. There's new science being developed all the time.

The plan that we're going to be issuing is meant to be a living document that will be updated at least every two years to reflect these changes. We will have an open docket for continuous feedback especially feedback from groups like AFDO. So let me just end by invoking the phrase, "May you live in interesting times."

We also live in very interesting times when it comes to food safety and nutrition. Opportunities and challenges abound and I think will continue to do so. So we all have our work cut out for us. And when say "Us" I really do mean "Us." Together.

So thank you for the work that you do. I'm delighted to be here and it's great to see everybody. I look forward to working with you.

USDA Food Safety Policy Changes
Carl Mayes
AFDO 121st Annual Educational Conference
Pittsburgh, PA – June 27, 2016

(Transcribed)

Facilitator: Hello again. As everybody filters back in, we will continue this morning. I would appreciate if you would be courteous and start to settle here in the room. If you want to carry on with the conversations, go ahead and step out. I would appreciate that.

Our next presentation here in the food track will be USDA Food Safety Policy Changes. Mr. Carl Mayes, Assistant Administrator, Office of Investigation, Enforcement and Audit at the US Department of Agriculture will deliver that and he has an impressive bio, 21 years in the Air Force among other things and I think that we would agree he's qualified to deliver this presentation.

I also just found out that he's apparently quite a celebrity and I tried to get in the line for the photo op. But I have to catch that up later. So let's welcome Mr. Carl Mayes.

[Applause]

Carl Mayes: Thank you. I'm glad to be here today with all of you from AFDO. You serve as leaders of our organization and agencies that share the same commitment to food safety as a food safety inspection service does.

Today I will provide you with a few regulatory updates and also discuss priorities for collaboration and then I will be happy to answer questions you may have. At FSIS, we're continuing our efforts to modernize our approach to food safety. This involves collaborating, communicating with the public including our partners and foreign governments, industry, stakeholder groups, states, local governments and academia.

As you know, FSIS's primary goal is to prevent food-borne illness by reducing pathogens in meat, poultry, and processed egg products. We also are working hard to build on modernization efforts and focusing on using science-based strategies to solve pathogen issues.

All of us here today are dedicated to improvements of our methods to protect the nation's food supply. Conferences like these present an opportunity to further collaborate with food safety professionals. The opinions and ideas that you have make a significant impact on the regulations and proposals that we work on.

So I'm talking about a couple of areas here. Outbreaks. One of our main priorities is to work closely with states before, during and after outbreaks. We had a conversation yesterday with some state partners on how we could work better together. FSIS's focus is on modernization. We're building systems like our public health information system, which provides us with real-time data.

So when we have something in the field come in, we can trace back and trace forward when to CDC and our Office of Public Health and Science (OPHS) who tracks outbreaks. We gather that information so we can quickly go to an industry firm or establishment and figure out – get their records and figure out where this product was made, when it was made, where it was shipped to and then hopefully we can get out of commerce as soon as possible.

It's very important that we increase collaboration with groups like AFDO, who share our goals for improvements in food safety. We have been working with AFDO in a number of states to try to set up an outbreak exercise here with a couple of states. I've been working with Stan on that. We will probably do some in August or September of this year if we can. We're going to start small and then we're going to try to increase throughout the years.

The reason why I want to do this is because a lot of times what happens is – and I heard yesterday the states don't necessarily know how we operate and sometimes we don't know how the states operate. So I think collaborating on an exercise is a perfect way to figure out, hey, this is how we do business. This is how they do business and once we learn how each other's – when we interact and participate together, we will get better at what we do together.

As a result, we will be working together on finding new ways that improve trace-back. One example of this is the shopper card information we've been doing. We've put a lot of data out last year. We started to try to gather more information on shopper card. We find that when a case patient is out there and they use the shopper card and we can get that information, it helps us do trace-back a lot easier because we know where they purchased it. We can track down the steps or number a little quicker.

Now, every state has different rules, especially dealing with PII. We need to make sure that we are able to get to that information as quickly as possible. Sometimes it's not possible, so we ask the states for that information

When a case patient reports they're sick, you are the first ones out there that talk to the case patient. You interview them. You get that information. That information is passed on to CDC. We get a number for that case patient and then we're a lot of times in wait mode. That's what a lot of people don't understand. As we're sitting there waiting for more information to come in, we really can't do a lot because we may not know the product. We may not have the pictures. We may not have the product yet. We may not have any more information with our case patient and hey, we have something going on. It's out there somewhere. It might apply to one state or multiple states.

So as we're waiting for more information to come in, that's when the communication and the collaboration between the states is very important. A lot of times what happens is, the states may call us and say, "Hey, what are you waiting on?" Well, we may be waiting on information.

So yesterday I heard it seems like sometimes we're running dual investigations. We're not really running dual investigations. As the states start out with the outbreak and we come in, we're gathering more information so we can support our case.

So there are things that we must make sure occur. We need to make sure that if testing is done and the samples are done correctly.

If we have statements from people in the firms, we want to make sure if this goes criminal, that we can support a criminal action against those people. A lot of cases what you find is when these firms – especially in mass outbreaks a lot of times, sometimes people take shortcuts and those shortcuts lead to problems. As those problems lead to people getting sick, we start investigating it as an outbreak. The next thing you know is a criminal investigation and we end up going to trial to convict someone for not doing something they should have been doing in the first place or they may have been modifying records to say this was what we were doing, even though that was a lie. We find that out a lot.

Along with other agencies such as FDC, FDA and CDC, we're working to improving estimates of food-borne illness source, attribution, derived from outbreak data. These can form efforts to prioritize food safety, initiatives, interventions and policies for reducing food-borne illnesses.

On that note, there's a great opportunity to further collaborate with organizations such as AFDO, especially in areas of recalls, illness, investigations, inspections and assessing whether retailers are practicing the best practices contained in FSIS guidance.

I talked to you yesterday about the daily guidance. We do need to work together to further that, to get that information out. I think it's important. I was reading on one of the displays out there, how some states have it mandatory. Some people use gloves. Others don't. We found yesterday, what I briefed on is we're finding that the retailers in these delis, sometimes the people are not washing their hands. They're not wearing gloves.

So if states have don't have these types of laws, that may be an area that we want to emphasize to those states that this is something you want to get the word out on to your people to do.

Food defense. FSIS has also been involved with several targets of food defense assignments. During previous and current national – we call them national security special events, including the upcoming democratic and republican national conventions. For these events right now, we collect samples. We've already done it for one convention. We're about ready to start for the other convention. We do this in preparation to make sure that the food that is served there is safe.

We know that chances are very low that anyone will get sick from this food. But we want to make sure that whoever goes to these things, that they're not targeted. So that's why we work these. We also work other events like the Super Bowl and the World Series.. We're there all the time making sure that whatever the consumers are going to consume, that we make sure that it's as safe as possible.

Prior to the events, we will be sampling approximately 100 samples as we take them from distributors to ensure the safety of all these attending the events.

We also have rapid response teams for recovery, to food safety and food defense events. So if something were to occur, we would be there on site and we would have people ready to go, to do trace-back and to find out what's going on.

Food-borne illness outbreak investigation plans and rapid response plans must be completed within 12 hours. So once we're notified something is going on at a certain location, the investigators have 12 hours to get their investigative plan in place. Then what happens is because we have investigators all over the United States and territories, I will make the decision or the regional director. Our regional directors make the decision that we will fly people or drive people in to help with that investigation.

So even though there may only be one person that you're used to seeing in that area, we can very quickly within 24 hours get as many assets in that area as we need to, to do the investigation.

Over the past few years, FSIS has made food defense a priority. Through collaboration with our industry, FSIS successfully promoted voluntary adoption of food defense plans by at least 85 percent of FSIS regulated facilities or establishments. This is an increase of 51 percent when we started in 2006.

We continue to do outreach to small and very small establishments and have developed a number of tools and resources to facilitate voluntary adoption of functional food defense plans. The threat of intentional contamination requires collaboration with a variety of partners and stakeholders across government industry and academia.

FSIS also works across USDA programs to promote adoption of food defense practices, address research needs and protect public health. This includes for example working with the Food and Nutrition Service to implement food defense practices as part of the National School Lunch Program, partnering with the agricultural research service to develop novel detection methods for emerging threats. Working with the agricultural marketing service to integrate food defense into commodity purchase programs and working with the Animal and Plant Health Inspection Service to address bio security practices from farm to fork supply chain.

Our domestic and local food suppliers are part of the global network. So we take that into account every time we do business out there. Key ingredients comprising foods in the U.S. may be sourced domestically or from other countries. So part of my job in also investigation and enforcement audit is I have the international auditors on my team.

So we go to the countries out there that have food systems that ship products into this country. We make sure those products are safe and that system is secure and so we have a three-year program. Usually if the program is deemed adequate, we go back every year. We look at your system. We go through and make sure you're doing exactly what you say you're doing, to make sure that your system is equivalent to ours. It does not mean they have to do the same thing. That means they have to show us what they're doing, how that's equivalent to what the United States is doing.

It's extremely important that we work within international community and trading partners to ensure the global food supply is safe and to protect it against contamination,

whether it's accidental, naturally occurring or intentional. We have a lot of incidents where when something comes in to our import houses, it is looked at. It can be rejected and sent back. Sometimes we're doing that right now. Some of the first Siluriformes fish products we got were from Vietnam. We found some residues in them. They were sent back. They weren't allowed to come into the United States.

We contact those countries. We ask them to look at that establishment and then we ask them, "OK, this occurred. What are you going to do to stop it?" and we also ask them how it occurred. So when we go back to audit them in the future, we're going to make sure that whatever they put in place, what they told us is true, and that this kind of occurrences stop from happening.

If an establishment in a foreign country keeps having problems, that country will remove them from the list to ship products into United States. So that goes on every day out there and most of that is done by our officer – the field operations are the ones that do those products, checks those products.

Much of our work focus is on creating new policies that will protect consumers. One example of this is our grinding logs rule that we published. The rule requires retail outlets and federal establishments to keep clear records on sources for ground beef products. These records will identify source, supplier, the names of all materials used in preparation of raw, ground beef products.

More record keeping will help improve trace-back capabilities and prevent food-borne illness. The final rule establishes expedited trace-back and trace-forward procedures that were announced in August 2014. These will allow FSIS to trace contaminated ground beef to the source more quickly by conducting immediate investigations at businesses with ground beef that test positive for E. coli 0157:H7 during initial testing and at suppliers that must be provided source material. So in other words, in the past, when we had outbreaks, we would go into a retail store let's say and we would say hey, we need to see your records on how you're grinding these materials together and they wouldn't have any records.

So the investigation would end at that point. We couldn't trace it back to an establishment. So what would happen is they would get multiple products from multiple establishments and they would grind it all together. So there was no way for us to know what was in the product that they gave that customer. So we put this rule in place. On June 20th the rule was implemented. It was put out there. It started. But we've already said come October 1st is when we're going to start enforcement.

The industry came to us and said – in response to the National Grocers Association—that they wanted a delayed enforcement. When we say we're going to delay enforcement it's because they asked us to go out there and educate people more on what was going to be required. They also said that some people weren't ready for the rule to take effect because they had to update their systems.

So FSIS agreed that that's when we said we would start October 1st enforcement of this rule. Now, the biggest thing about this is we say – when we put this rule out there, it's going to help with trace-back and trace-forward. We need those grinding logs because

when an outbreak occurs, that's one of the first things that we grab to make sure that we can trace it back to where the source is coming from.

So even though we're delaying this rule, they still need to be doing this. They still need to make sure that they're working towards getting their grinding logs in place because it's only going to save us lives by being able to get that product out of commerce quicker, by being able to trace it back.

So we know it's out there. We're going to do some more training. Our Office of Policy and Program Development (OPPD) is always working on getting training out there about grinding logs to educate the consumers and the businesses more. So therefore we think when we implement this or actually enforce them on October 1st, we will be better off.

Mechanically-tenderized beef. Recently, we've completed a number of modernization initiatives and I wanted to briefly cover some of those. You may know that mechanically-tenderized beef rule that FSIS published last year. The new requirements became effective last month, one year from the date of the rules publication of federal registry.

This rule will identify mechanically-tenderized beef products to consumers and will add new cooking instructions so that consumers and restaurants can prepare these products safely.

Research has shown that mechanical tenderization process may transfer pathogens from the outset of the meat into the meat which poses a greater risk of public health than beef products.

So under the final rule, mechanical tenderization products must bear labels that state that they have been mechanically blade or needle-tenderized. The labels must also include validated cooking instructions so that consumers know how to safely prepare these products.

The instructions will have to specify the minimum internal temperatures and any hold or dwell times for the products to ensure that they're fully cooked. It only makes sense that we make instructions clear for consumers and restaurants. We see less illnesses when people are better-educated and prepared. I will tell you that, within FSIS, we talk about labels a lot. We have a "safe handling" initiative right now to look at labels if the information is correct. So they're going to be working at this for the next couple of years to figure out how we need to change these labels, if they need to be updated, and what information needs to be on there for consumers so they know that product is safe.

We had an outbreak with chicken products that were not cooked properly. The boxes told the consumers, hey, you need to cook these products in an oven, not a microwave. Some of the consumers said they might have used the microwave. Others said they cooked it properly. They followed directions and people still got sick.

So even though the labels, as best as that company could do, it still was not clear to some people that they need to follow those instructions. So we always are looking at ways to better the labels and better the information that can be provided on those boxes for the consumer to know how to cook those products properly.

We have new performance standards. This past February, the agency released a new final standard for Salmonella and Campylobacter in ground chicken and turkey products as well as in raw chicken, breast, legs and wings. This approach to poultry inspection is based on science, supported by strong data and the truly improved public health.

For chicken parts, ground chicken and ground turkey, FSIS is finalizing the pathogen reduction performance standard designed to achieve at least a 30 percent reduction in illnesses from Salmonella. In alignment with overall Healthy People 2020 goals, USDA expects these actions to prevent as many as 50,000 food-borne illnesses annually.

So another thing we're working on right now in FSIS is our Strategic Plan. Our current one runs on Fiscal Year (FY) 16. The new one will be five years starting at FY 17. We've been working with other agencies to help develop this plan and internally we've been looking at different ways of what we're going to do to help reduce illnesses out there. So that plan should be coming out pretty soon for everyone to see and like I said, we will implement in FY 17. So you will be seeing that pretty soon.

So in conclusion, it takes cooperation from government, scientists, educators, consumers, industries and others to protect public health most effectively. This cooperation is necessary when dealing with complex issues of food safety. Individuals and organizations all have valuable input and a different way of looking at things. We at FSIS really appreciate the value of all the hard work you do at AFDO. Thank you for all your great efforts and I will now take time to answer any questions you may have. Any questions?

[Participant raises a question]

Carl Mayes: We're going to look at livers. We have – we just approved a plan to go in there and do a study of that, to figure out if that is the problem or if it's something else.

[Participant raises a question]

Carl Mayes: So I would say yes to our plans. But it never hurts – we have an Office of Outreach, Employee Education, and Training – you can contact and they would help design some kind of program, some kind of other stuff to put out there. When we file federal regulation and those rules, they apply to the federal government. They're not being implemented on the state.

Now obviously the establishments, retailer, whatever in those states, have to follow those rules, so the states will be impacted somewhat. But like grinding logs, that is a federal thing. So if the states don't require it but the federal government does require it, the state doesn't necessarily have to go on there and look at it.

Now I would think though if an outbreak or something occurs, that doesn't get to the level of FSIS, the states would use that same information to trace back or trace forward, whatever they're doing in that area. So it's going to help them also. Yes.

[Participant raises a question]

Carl Mayes: So at these major events like the Republican and I Democratic conventions coming up and other ones that we did like Nuclear Summit that just took place, DHS and FDA are at the table leading those. We are just a partner there. So it's a team effort to bring everyone together to make sure that these places are safe.

We do our stuff for food. FDA does their stuff. DHS does their stuff. But we all know what everyone is doing. That way, no one is getting left out and we're not missing anything. So yes, there is conversation at that level. Any other questions?

I want to thank you – and just remember, we had our meeting yesterday and what I said is as the AA for Office of Investigation, I'm willing to send my investigators anywhere and a lot of you that are on the right response teams in the states know that I have investigators that show up there at the meetings and stuff and they will discuss things with you.

The biggest thing we run into is every state is different and the rules are different and how you are organized is different. We just need to make sure we're talking to the right people at the right time. What I see a lot of times is I will have someone from one state come in and say, "Hey, you guys aren't talking to us. We don't know what's going on." But I will have my people say, "Well, I'm talking to so and so and the state."

So communication makes a difference. Even though you're in the same state, you're not talking to each other and we don't know any better. So we're not talking to you either. So we need to make sure that we understand the organization of the states that we're talking to the right people, bringing them at the table together and in that way, we can always cooperate together and collaborate better together. All right. Thank you. Thank you.

[Applause]

FDA's Quality Agreement v. EMA's cGMP Chapter 7 Outsourcing

An Article for AFDO

By John Avallanet, Managing Director/Principal
Cerulean Associates, LLC

In November 2016, the US Food and Drug Administration (FDA) finalized a guidance long sought by industry. *Contract Manufacturing Arrangements for Drugs: Quality Agreements* describes the FDA's current expectations for firms that outsource the production of commercial drug products subject to current Good Manufacturing Practice (cGMP) regulations. The original draft version of this guidance was published in 2013, five months after the European Union's new cGMP regulations went into effect.

How does the FDA's final guidance stack against the regulatory rules that have been enforced by the European Medicines Agency (EMA) since 2013? Can we comply with both or are there gaps enough that risks abound?

Guidance Scope

Pharmaceutical, biotechnology and veterinary medicines firms have long pushed FDA to publish guidelines on how outsourcing of regulatory responsibilities should be set up and documented. The calls for this guidance became even more strident after the European Union (EU) published its draft version of its revised cGMP regulations that formally went into effect at the end of January 2013.

At thirteen pages, FDA's guidance is longer than the EU's revised cGMP rules governing contractual relationships, Chapter 7 of the EU cGMP. While a cursory glance at FDA's guidance might lead one to think the focus is strictly on contract manufacturing of a finished drug product, early on, the FDA clarifies that this guidance applies to manufacture of "human drugs, veterinary drugs, certain combination products, biological and biotechnology products, finished products, APIs, drug substances, in-process materials, and drug constituents of combination drug/device products" intended for commercial sale and/or distribution.¹

The guidance does not currently apply to firms developing new drugs nor those designing or producing medical devices, except for those firms involved in combination products. While it would be ideal to claim that only those firms involved in commercial production need concern themselves with the guidance, the reality is slightly different. Because firms in clinical production, and in particular late stage production, often use the same contracted facility for commercial production, executives in drug development firms would do well to pay heed to the guidance. Indeed, during a pre-approval inspection, FDA investigators will be well-aware of the FDA's guidance and will ask about contractual relationships with a firm's cGMP suppliers. If nothing else, ignoring the guidance during late stage clinical production is a significant risk.

As is made clear in the examples provided throughout the guidance, the list of contracted suppliers for whom a firm should have quality agreements includes not only specific facilities that actually make the product, but also contracted laboratories involved in cGMP activities, contracted packaging and warehousing facilities involved in cGMP activities, and contract sterilizers. In one of the later examples, it is evident that if a firm contracts

out its systems and applications to a hosted environment throughout which cGMP data is created or stored (these often fall under the umbrella phrase “operations of the Quality Unit” as such data includes quality control data, release information, etc.), such hosted information technology (IT) suppliers may also need a quality agreement.

The scope of the guidance becomes clear upon full review, and dovetails with the opening statement of the EU cGMP Chapter 7: Outsourced Activities, “Any activity covered by the GMP Guide that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality.”² FDA adds that quality agreements are intended to “ensure compliance with cGMP.”³

Responsibility v. Accountability

While the EU cGMP Chapter 7: Outsourced Activities defines the roles of the two parties in a contract as the “Contract Giver” and the “Contract Acceptor,” the FDA has taken a more nuanced approach.

To FDA, the Contract Giver is the drug product “Owner” and the Contract Acceptor is the “Contract Facility.” Part of this approach has to do with FDA’s ability to rely upon well-established, nationwide product liability rules in the US: regardless of who gave or accepted a contract, the organization who “owns” the product introduced into commerce is accountable under US law. In other words, if you own the intellectual property or the trademark or the market license, you are the product Owner to FDA.

The second reason for FDA’s more nuanced approach is the agency must also be able to enforce cGMP requirements on those suppliers whose activities would normally fall under cGMP regulations regardless of the existence of a “Contract Giver.” Because some suppliers to the industry, such as API makers, contract manufacturers, and so on, already fall under FDA regulations, some in the pharmaceutical and biologics industry had hoped to simply transfer their own accountability for cGMP compliance to a contracted facility; in other words, to outsource regulatory compliance to a supplier.

Instead, FDA’s quality agreement guidance has made clear that the product Owner retains ultimate accountability both for regulatory compliance and for drug quality, safety, and efficacy: “It is important to note that quality agreements cannot be used to delegate statutory or regulatory responsibilities to comply with cGMP”⁴ and “No party to a quality agreement may delegate any of its responsibilities to comply with cGMP through the quality agreement or any other means.”⁵ This is yet another reason that executives in firms currently in clinical development and manufacture may want to review this guidance; any business plan that relies upon outsourcing commercial product compliance to a contract manufacturer is going to lay in troubles ahead.

FDA clearly states that outsourcing accountability is not only illegal, but that if companies try to get around this by mutually negotiating a transfer of accountability in a quality agreement, this will also be held by the agency as a violation of the Food, Drug and Cosmetic Act (FD&C Act).

In the days leading up to the original draft guidance’s publication, FDA emphasized the inability of firms to delegate accountability by issuing five Warning Letters to firms for

trying to do just this: Natures Health Options,⁶ Body Systems,⁷ Gucorell,⁸ Pristine Bay,⁹ and Entrenet Nutritionals.¹⁰ In each of these Warning Letters, FDA cites the Park Doctrine (from *United States v. Park*, 1975) to hold the firms and their management accountable for criminal wrongdoing even though they delegated cGMP work task responsibilities to their suppliers through contracts.

To the FDA then, the Contract Facility is only responsible for completing the actual work tasks as delegated by the product Owner. The product Owner is accountable for the compliance of those work tasks and for the quality, safety, and efficacy of any resulting drug product.

In other words, it is the company officers of the product Owner who are liable for any violations of the cGMP and FDCA occurring during the production of their drug, irrespective of who – a product Owner’s own employees or a supplier’s employees at a Contract Facility – actually violated the law or regulation. To those with familiarity with the Park Doctrine or product liability litigation, this should come as no surprise.

That said, however, the FDA guidance makes clear that a Contract Facility which would normally also have to comply with the cGMPs and the FDCA may still potentially be in trouble for allowing an unsafe or ineffective product to be produced at their facility or a non-compliant process to continue to be followed: “A quality agreement cannot exempt owners or contract facilities from statutory or regulatory responsibilities to comply with applicable cGMP, regardless of whether the quality agreement specifically discusses those cGMP requirements.”¹¹

Thus, the FDA would be able to issue two Warning Letters: one to the product Owner for breaking the cGMPs and the FDCA, and one to the Contract Facility for complicity and agreeing to manufacture in a non-compliant manner.

Technically, the EU revised cGMP Chapter 7: Outsourced Activities also identifies ultimate accountability as lying with FDA’s product “Owner” (the EU’s “Contract Giver”), “The Contract Giver is ultimately responsible....”¹²

Role of the Quality Unit

For small companies and so-called virtual pharma firms, FDA’s insistence on product Owner accountability comes at a price. Many such virtual pharmas have entirely outsourced their Quality Unit to suppliers; this is integral to their current business model and does entail some costly changes, including having to hire a quality professional in some capacity.

Having a contract manufacturer produce a drug product batch, quality control check the batch, and then release the batch, all without knowledgeable, informed input and approval from the product Owner is clearly problematic under the guidance: “When an owner uses a contract facility, the owner’s quality unit is legally responsible for approving or rejecting drug products manufactured by the contract facility, including for final release.”¹³ How will a small or virtual pharma, who may have no knowledgeable quality professional be able to review and release finished drug product without reliance on the contract manufacturer’s personnel or some other outside entity?

The EU rules rely upon the role of the independent Qualified Person (QP) under the Contract Giver to release each batch of product. FDA does not have this QP concept, although one could read aspects of the guidance, particularly the Quality Unity responsibilities section, as inching toward assigning similar roles of the EU's QP to the Quality Unit.

One means for a small or virtual pharma to comply with the FDA guidance and the EU's revised cGMP regulations is for the product Owner to hire an independent individual or organization to serve as a Qualified Person so as not to rely solely upon the Contracted Facility's internal Quality Unit. If your firm is considering this approach, review the EU rules and guidance on selecting a Qualified Person—and then make sure to qualify that individual as a supplier.

For FDA compliance purposes alone, there are many ways in which an independent, Owner-provided Quality Unit could be achieved – periodic sampling and testing of finished product through separately contract laboratories, frequent onsite audits that always review production and batch release processes and records, and so on. The key is that the product Owner is not allowed to outsource sole finished product release to the same Contract Facility that made the finished product.

Defining a Quality Agreement

In the guidance, FDA defines a quality agreement as establishing “...the respective cGMP-related roles, responsibilities, and activities in drug manufacturing.”¹⁴ The impetus for quality agreements comes from several cGMP guidelines published by the International Conference on Harmonization (ICH), specifically *Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients* (2000), *Q9: Quality Risk Management* (2005), and *Q10: Pharmaceutical Quality System* (2008). Note that in the EU's revised cGMP Chapter 7: Outsourced Activities, the EU specifically cites the ICH Q10 guideline as a driving reason for its revision of Chapter 7 and the controls therein.

FDA recommends that quality agreements should not be mixed into commercial or business agreements covering issues such as pricing, liability limitations, and so on. And just as a confidentiality agreement is usually severable from a commercial agreement, although still incorporated by reference, so too should a quality agreement be severable from other contractual agreements.

That said, FDA is clear that a quality agreement is meant to be a legally binding agreement and not an agreement simply between quality departments at the product Owner and the Contract Facility; indeed, FDA has cited firms in FDA-483s for such written “gentlemen's agreements” as being non-enforceable and non-binding.¹⁵

The agency sees a quality agreement as a legally-binding contractual document on par with a stand-alone mutual non-disclosure agreement or a commercial contract. Interestingly, in the original draft guidance, the agency referenced its use of income tax information from the US Internal Revenue Service (IRS) to help determine the quality agreements FDA expects between a product Owner and its commercial suppliers.¹⁶

Thus, for a product Owner with six different suppliers falling under the scope of the quality agreement guidance, FDA would expect the firm to have six different commercial contracts and six corresponding quality agreements, all mutually negotiated and legally executed by officers of each company. Given the relationship of a quality agreement to product liability and compliance with the FD&C Act as revised by the Food and Drug Administration Safety and Innovation Act (FDASIA), it is imperative for Quality Unit professionals to understand that quality agreements are legally binding contracts that FDA investigators will expect to see during inspections.

Likewise, the EU revised Chapter 7: Outsourced Activities points out that contractual agreements on activities under the cGMP, not just the regulated processes themselves, are “...subject to inspection by the competent authorities.”¹⁷

Practical Structural Elements

In its guidance, the FDA recommends that a quality agreement contain five core elements:

- 1) Purpose and scope
- 2) Terms (including effective and termination dates)
- 3) Provisions for dispute resolution
- 4) Responsibilities for the product Owner versus the Contract Facility
- 5) Managing change and revisions.¹⁸

Buried throughout the section discussing these elements (section IVB of the guidance), FDA alludes to a further un-enumerated critical element that is likely to be the source of future FDA-483 observations and Warning Letters if not addressed adequately: How firms plan to handle deviation investigations (i.e., CAPAs).

Because corrective and preventative actions (CAPAs) are a common high priority target during inspections, consider “Handling and communicating deviations” as a sixth core element. Expect to see FDA investigators examine deviations at a Contract Facility to see if blame can be assigned to the product Owner for poor supplier oversight, introduction of an adulterated product into interstate commerce, and violating the tenets of the Park Doctrine (along with expectations stemming from *United States v. Dotterweich*, 1943).

FDA devotes several pages in the guidance to discussing delegation of work task responsibility and managing change. Aside from ensuring product Owner accountability and examining how deviations are communicated, investigated, and resolved under a quality agreement, responsibilities for work task completion and change management are two areas most likely to draw FDA investigator scrutiny.

Delegation Clarity

As discussed earlier, the Contract Facility (e.g., the Contract Acceptor) is only responsible for carrying out the outsourced work tasks. The product Owner (e.g., Contract Giver) retains accountability for compliance and product quality, safety, and efficacy.

FDA expects to see this clearly spelled out in the quality agreement. The agency suggests that one method is to track the subparts of the cGMP regulation and list who is responsible for what activity under each subpart.¹⁹ This is similar to the current Good Clinical Practice (cGCP) approach for documenting responsibility and delegation of clinical

trial activities. In delegating clinical trial activities, many firms take a simple grid approach, and this can be applied to a quality agreement as well, with a result that might look like Table 1.

Table 1: Task Responsibilities

Work Task	Owner	Contract Facility
Approval of drug product containers and closures	X	
Receipt of untested drug product containers and closures		X
Storage of tested drug product containers and closures		X

Throughout its discussion of responsibilities, FDA identifies many items the product Owner should incorporate into an audit of a potential Contract Facility including cross-contamination controls, traceability controls, equipment maintenance, and environmental monitoring. Likewise, the EU’s revised cGMP Chapter 7: Outsourced Activities identifies several similar areas of concern which should be expected to come under inspection scrutiny: “The Contract should describe clearly who undertakes each step of the outsourced activity, e.g. knowledge management, technology transfer, supply chain, subcontracting, quality and purchasing of materials, testing and releasing materials, undertaking production and quality controls (including in-process controls, sampling and analysis).”²⁰

Change Control Clarity

FDA expects a quality agreement to clearly identify specific types of changes in which the product Owner must be involved. FDA is not a fan of all encompassing, blanket “all changes” phrasing as this leaves far too much open to interpretation. FDA expects a quality agreement to identify three specific types of changes:

- 1) Changes that require product Owner review and approval prior to the change
- 2) Changes that require product Owner notification only
- 3) Changes that do not require involvement or notification.²¹

In all three cases, changes should only be those that fall within the scope of the outsourced activities delegated from the product Owner to the Contract Facility. And in the case of changes not requiring either Owner review/approval or notification, FDA expects such changes to present little to no risk to product quality, safety or efficacy, or to regulatory compliance. As an example, FDA expects that the product Owner will have some degree of input into, review and approval of a Contract Facility’s standard operating procedures (SOPs) and policies that directly relate to or govern the delegated work tasks.

In this light, FDA suggests that product Owners give serious consideration to “...including the contract facility’s established processes and procedures as part of the quality agreement (for example, by incorporating certain standard operating procedures by reference). Doing so could reduce the risk of misinterpretation or error during manufacturing.”²² In other words, FDA has recognized an inconvenient reality: rather than encouraging standardization and control, the more a product Owner foists its own

SOPs onto suppliers, the greater the likelihood of error, the more deviation investigations, and more change controls that will be necessitated, driving down product quality, safety, and efficacy, and reducing compliance. Thus, FDA suggests adopting a supplier's own SOPs while retaining change involvement for those SOPs that directly impact or govern the delegated work tasks.

The EU's cGMP Chapter 7 only alludes to the need for change to be managed and controlled, "The Contract Acceptor should not make unauthorized changes, outside the terms of the Contract, which may adversely affect the quality of the outsourced activities for the Contract Giver."²³ So for change management, complying with FDA's guidance on controlling changes will also ensure compliance with the EU's change control expectations in its revised cGMP on outsourcing regulated activities.

Five Hidden Requirements

Embedded within the FDA guidance are five requirements that may come as a surprise to those who simply skim the guidance:

- 1) Risk review
- 2) Record ownership
- 3) Part 11 compliance
- 4) "Drug/site master file-esque" appendix
- 5) Auditing.

First, as part of supplier selection, a product Owner needs to conduct a risk review to determine the type and extent of controls to be associated with a supplier (e.g., Contract Facility) and thus the degree of detail necessitated in a quality agreement.²⁴ This stems from FDA's current interpretation of how firms should be implementing the ICH guidelines. Those aware of the Purchasing Controls section of 21 CFR 820.50 will see similarities in this guidance's expectation of risk-based supplier oversight.

Second, the records resulting from all outsourced activities – batch records, incoming materials acceptance, analytical test results, etc. – all belong to the product Owner. Care needs to be given to ensure the right records (either from or at the supplier) are retained for the right length of time under the right conditions to ensure long-term integrity. Proper records retention and integrity falls in line with FDA recordkeeping requirements and helps mitigate some of the risks associated with product liability litigation. Within the "Documentation" subsection of the draft guidance is the between the lines expectation that firms have a procedure on to make and maintain true copies of cGMP-required records.²⁵ This SOP and others associated with good FDA recordkeeping and data integrity are essential controls to address in the quality agreement.

Third, cGMP-related records – if kept digitally – are to "be stored in accordance with cGMP and will be immediately retrievable during the required record-keeping timeframes..."²⁶ In other words, the quality agreement should identify and document how the product Owner and the Contract Facility will ensure data integrity throughout the data lifecycle, from original data creation through long-term archival, and the compliance of any digital records with 21 CFR 11 Electronic Records; Electronic Signatures (e.g., Part 11). In addition, this requirement also falls in line with FDA's New Inspection

Protocols Project (NIPP) wherein inspections are conducted using digital records and webinar access to remotely hosted systems.

Fourth, an appendix within the quality agreement should incorporate many elements normally found in a drug master file. Specifically, this should include "...product/component specifications, defined manufacturing operations, including batch numbering processes..."²⁷ Those familiar with drug master file contents, quality by design, or even device master records will recognize FDA's intent: verifying that the Contract Facility and product Owner have agreed upon and documented critical product quality attributes (CQAs) and critical process quality parameters (CPPs). FDA's guidance subtly encourages a further march toward full implementation of quality by design.

Fifth, the Agreement must document the ability of the product Owner to audit the Contracted Facility and its outsourced cGMP activities relevant to the product Owner, "Quality agreements should also cover audits, inspections, and communication of findings. The agreement should allow owners to evaluate and audit contract facilities to ensure cGMP compliance for specific operations."²⁸

At first glance, this requirement might seem to imply that the product Owner has to assume liability for the overall cGMP compliance of a supplier. However, careful reading identifies that this auditing for compliance is specific to those operations actually outsourced to a supplier. Whether this also carries with it an expectation that "implementing processes" such as training are also technically considered "outsourced" (even if not specified in a contract) are largely dependent the scope of the outsourced activities. A prudent Owner should assume that the use of qualified personnel at the Contracted Facility is a responsibility of the Owner to at least verify.

All five of these "hidden" requirements are either stated outright or are otherwise implied in the EU's revised cGMP Chapter 7: Outsourced Activities. The EU specifically states that supplier controls are to be based upon an evaluation of the risk of the supplier and its impact to product quality, safety, and efficacy is captured early on: "The Contract Giver is ultimately responsible to ensure processes are in place to assure the control outsourced activities. These processes should incorporate risk management principles..."²⁹

Documentation and records are addressed in § 7.16, "All records related to the outsourced activities, e.g. manufacturing, analytical and distribution records, and reference samples, should be kept by, or be available to, the Contract Giver."³⁰ Note that the EU regulations go further and require that such record types should also be delineated in the "relevant procedures of the Contract Giver" (i.e., the SOPs of the product Owner should identify the types of records produced by following the procedure).³¹

And the integrity of electronic records is embedded as compliance with Annex 11 in §§ 7.8 and 7.10, "The Contract Giver should be responsible for reviewing and assessing the records and results related to the outsourced activities. He should also ensure...that all products and materials [including data] delivered to him by the Contract Acceptor have been processed in accordance with GMP and the marketing authorization"³² and "The Contract Acceptor should ensure that all products, materials and knowledge delivered to him are suitable for their intended purpose."³³

Quality by Design and drug master file elements are incorporated by definition into the phrase “all information and knowledge necessary” found repeatedly throughout Chapter 7.

And in terms of auditing, the EU regulations specify that the “Contract should permit the Contract Giver to audit outsourced activities performed by the Contract Acceptor or his mutually agreed subcontractors.”³⁴

Subcontracting

Interestingly, it should be recognized that in one area, FDA’s guidance does not go as far as the EU regulations: subcontracting.

The EU regulations unequivocally state “The Contract Acceptor should not subcontract to a third party any of the work entrusted to him under the Contract without the Contract Giver’s prior evaluation and approval of the arrangements. Arrangements made between the Contract Acceptor and any third party should ensure that information and knowledge, including those from assessments of the suitability of the third party, are made available in the same way as between the original Contract Giver and Contract Acceptor.”³⁵

FDA simply states that “The Contracted Facility should notify the Owner of changes, including but not limited to, raw materials and starting materials and their suppliers....”³⁶ This may work for general tier 2 and further suppliers, but it is insufficient to protect product Owners from suppliers who turn to shadow facilities and shady subcontractors. For firms increasingly worried about the long tail of their pharmaceutical supply chains, they should look to the EU’s revised cGMP regulation for advice.

Final Thoughts

As you can see, the FDA’s final guidance on quality agreements requires thoughtful analysis. Retaining accountability while outsourcing both responsibility and, possibly, knowledge (i.e., batch release), is a significant risk to manage. Given the intent of a solid quality agreement – “...to delineate manufacturing activities for ensuring compliance with cGMP”³⁷ – a well-crafted quality agreement can be worth its weight in gold.

This is especially true in light of the FDA guidance’s clear similarity to the EU’s revised cGMP regulation Chapter 7: Outsourced Activities. Whether the guidance document will be enough, or will require more FDA Warning Letters and product seizures, remains to be seen. The suggestions and analyses in this article should help you avoid trouble and inefficiencies by making the most of the FDA guidance and the cGMP EU rules.

¹ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, page 2.

² European Commission, Health and Consumers Directorate-General, *Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Chapter 7: Outsourced Activities*, June 2012, page 1.

³ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, page 1.

⁴ *Ibid*, page 6.

⁵ *Ibid*, page 7.

⁶ FDA Warning Letter dated 2 April 2013, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351946.htm>, accessed on 22 November 2016.

⁷ FDA Warning Letter dated 8 April 2013, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351883.htm>, accessed on 22 November 2016.

⁸ FDA Warning Letter dated 24 April 2013, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm352011.htm>, accessed on 22 November 2016.

⁹ FDA Warning Letter dated 26 April 2013, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm350469.htm>, accessed on 22 November 2016.

¹⁰ FDA Warning Letter dated 8 May 2013, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351662.htm>, accessed on 22 November 2016.

¹¹ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, pages 11-12.

¹² European Commission, Health and Consumers Directorate-General, *Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Chapter 7: Outsourced Activities*, June 2012, § 7.4, page 1.

¹³ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, page 4.

¹⁴ *Ibid*, pages 5-6.

¹⁵ Speeches by Hidee Molina and Kim Trautman as cited in “Current FDA Supplier Control Expectations,” *SmarterCompliance* newsletter, Vol. 5, Issues 9-10, 2011, pages 5 and 10.

¹⁶ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, draft guidance, May 2013, page 5.

¹⁷ European Commission, Health and Consumers Directorate-General, *Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Chapter 7: Outsourced Activities*, June 2012, § 7.13, page 2.

¹⁸ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, pages 6-11.

¹⁹ *Ibid*, pages 7-11.

²⁰ European Commission, Health and Consumers Directorate-General, *Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Chapter 7: Outsourced Activities*, June 2012, pages 2-3.

²¹ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, pages 10-11.

²² *Ibid*, pages 6-7.

²³ European Commission, Health and Consumers Directorate-General, *Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Chapter 7: Outsourced Activities*, June 2012, § 7.4, page 2.

²⁴ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, page 5.

²⁵ *Ibid*, page 10.

²⁶ *Ibid*.

²⁷ *Ibid*, page 9.

²⁸ *Ibid*, page 8.

²⁹ European Commission, Health and Consumers Directorate-General, *Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Chapter 7: Outsourced Activities*, June 2012, § 7.4, page 1.

³⁰ *Ibid*, page 3.

³¹ *Ibid*.

³² *Ibid*, page 2.

³³ *Ibid*.

³⁴ *Ibid*, page 3.

³⁵ *Ibid*, page 2.

³⁶ FDA, *Guidance for Industry – Contract Manufacturing Agreements for Drugs: Quality Agreements*, November 2016, page 4.

³⁷ *Ibid*, page 13.

Effective Writing Sets You Apart in the Health Care Field: A How-To Guide

By Daniela Drago, PhD¹, and Nancy Singer, JD, LLM¹.

Today's professionals in the health care field are busy. Some of them might think that taking the time to improve their writing is just too hard. However, knowing how to skillfully craft a document is essential to communicating effectively and advancing one's career.

The National Commission on Writing surveyed more than 100 major corporations in the United States. In a report, the Commission found that business writing skills strongly influence an organization's decisions to hire or promote individuals, and poor communication skills are critical factors to deny promotions.²

In this article, Professors Daniela Drago and Nancy Singer provide advice on how you can write documents that readers will comprehend quickly and easily.

The Purpose of Writing in the Health Care Field

Please select the letter that provides the best answer to this multiple-choice question:

What is the purpose of writing in the health care field?

- a) To impress the reader with your intellect by using big words and long, complicated sentences.
- b) To erect a barrier where you create distance from the reader.
- c) To demonstrate your wit by using sarcasm in your writing.
- d) To help the reader understand your message easily.

Obviously, the answer is d) - to help your reader understand your message easily. Unfortunately, many people at one time or another have written documents that would fit within the descriptions of a, b, or c.

You can have great ideas, but unless you can communicate them effectively, you will not receive the recognition that you deserve. Writers at times falsely believe that to use a long, complex word rather than a short, simple one is a sign of intelligence. It's not. Author Robert D. Smith notes, "People are doing you a favor by reading what you write. Don't make them work too hard."³

¹ Department of Clinical Research and Leadership, School of Medicine and Health Sciences, The George Washington University, Washington, DC, USA

² The National Commission on Writing, *Writing: A Ticket To Work... Or A Ticket Out. A Survey Of Business Leaders*. CollegeBoard, 2004. Web. 8 Nov. 2016 (http://www.collegeboard.com/prod_downloads/writingcom/writing-ticket-to-work.pdf).

³ Smith, Ronald D. *Becoming A Public Relations Writer: Strategic Writing For Emerging And Established Media*. 5th ed. Routledge, 2016. Print.

In the health care industry, where companies are required to provide written evidence that they have complied with prescriptive regulations, clear communication is essential. Government officials need to write understandable requirements, and industry officials have to explain precisely what their companies did to meet those requirements.

The Government's Requirement to Write Clearly and Use Plain Language

For more than fifteen years, the government has recognized the need to use plain language. In 1998, President Clinton issued an executive memo requiring agencies to write in plain language. Vice President Gore created the "No-Gobbledygook Award."⁴ In 1999, he presented the award to the FDA for the over-the-counter drug labeling requirements. Mr. Gore noted that the new rule "will ensure that the labels on medicine we buy over the counter are no longer written in language that is over our heads. Starting here and now, when children wake up sick in the middle of the night, parents won't have to read a dictionary to read the directions. And people won't need a magnifying glass to find out what's in their medicine."⁵

On October 13, 2010, President Obama signed the Plain Writing Act of 2010.⁶ The law requires that federal agencies use clear written communication that the public can understand. The government's website - <http://www.plainlanguage.gov/> - explains the history of the plain language initiative, and provides resources to help government officials and the public provide training in this area.⁷

Characteristics of Effective Written Communication

To create a more effective workplace, and avoid misunderstandings, both government and industry employees need to write documents that are complete, correct, concise, credible, and courteous. Here are some suggestions on how to write documents that satisfy each of these characteristics.

Complete

Before you start writing, you need to consider what you want to say. If you employ the stream of consciousness method to compose your documents, you may find that your correspondence is unstructured, circuitous, and incomplete. One way to make sure you have included all of the information that your reader would want to know is to use the reader-centered question method. Ask yourself "what would my reader want to know from this email, request, report, or proposal?" Then you should:

- Write the questions that the reader would have about your topic.
- Write the answers.
- Group the questions and answers under headings.
- Write the document.

⁴ "Plain Language: Award-Winners". *Plainlanguage.gov*. N.p., 2016. Web. 8 Nov. 2016.

⁵ "Plain Language: Award-Winners". *Plainlanguage.gov*. N.p., 2016. Web. 8 Nov. 2016.

⁶ H.R.946 - 111Th Congress (2009-2010): Plain Writing Act Of 2010". *Congress.gov*. N.p., 2016. Web. 8 Nov. 2016.

⁷ "Plain Language: Improving Communications From The Federal Government To The Public". *Plainlanguage.gov*. N.p., 2016. Web. 8 Nov. 2016.

A good practice is to show the document to your colleagues. Then, ask them if you have answered all of the questions they might have about your subject.

Correct

If your documents contain grammatical errors, your reader will be confused. To proofread your document and find your errors, you should consider using one or more of the following techniques:

- Read your document out loud.
- Read your document backward.
- Enable the text-to-speech tool on your computer. This tool lets your computer read your document to you.

Concise

Readers have an easier time reading short sentences with small words instead of long sentences with large words.

For example, rather than having to read the sentence -

"It is much more highly advantageous and beneficial to furnish inherent and external value to others than to participate in accepting the magnanimous, generous, and altruistic gifts provided by others."

You would prefer to read

"It is better to give than to receive."

Credible

To convince your reader, you need to support your statements with evidence. You can quote authoritative publications, provide statistics, or illustrate your point with examples.

Authoritative Publications

Instead of writing – "Device manufacturers are required to identify the training needs of their employees and ensure that their personnel are trained to adequately perform their assigned responsibilities."

Write – "The FDA regulation, 21 CFR section 820.25 (b), requires that device manufacturers establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities."

Statistics

Instead of writing – "FDA filed more injunctions in 2015 than in 2014."

Write – "According to FDA's website, FDA filed 21 injunctions in 2015 and 10 injunctions in 2014. This represents a 110% increase."⁸

⁸ Source: <http://www.fda.gov/downloads/iceci/enforcementactions/ucm484400.pdf>

Examples

Instead of writing – "I deserve a bonus."

Write – "I deserve a bonus. I have fulfilled all obligations in my job description (see attachment 1). I have exceeded my goals for the year (see attachment 2). Additionally, I have taken on numerous new responsibilities such as mentoring three new employees, creating the organization's document retention program, and creating a supplier quality program that saved the company over \$300,000 in components' cost."

Courteous

Workplaces are more productive when people get along, and the atmosphere is positive. Instead of erecting a barrier between you and the reader, you should try to communicate warmth, kindness, and respect, so readers can grasp the content of our messages without reacting emotionally.

Instead of writing – "I have placed the burden on you to notify me expeditiously in four calendar days if you will need to modify the document."

Write – "Please let me know by Friday if you will need to change the document."

Instead of writing – "I don't really care at all whether or not you like it, just do it!"

Write – "Let's schedule an appointment and discuss why this task is required."

Conclusion

Government and industry officials in the health care products industries need to write emails, reports, and proposals. They should use plain language and write documents that are complete, correct, concise, credible, and courteous.

Writing is not a talent you are born with, but a skill that can be learned. If you practice – and build time into your schedule for writing, editing, and revising - you will see improvements. Your efforts are likely to be rewarded, because good writers distinguish themselves on the job, and increase their chances for advancement.

Summary of Retail Food Inspection Scoring, Grading, or Placarding Systems

Jennifer Li, MHS and Amy Chang, MS

Introduction

As more Americans eat out and the number of retail food establishments increases, the concern for food safety also increases. To help prevent foodborne disease, retail food regulatory programs license and inspect retail food establishments. Some retail food regulatory programs have incorporated a scoring, grading, or placarding system as part of their regulatory approach. These systems vary between states and may even vary among localities within the same state.

The National Association of County and City Health Officials (NACCHO), with support from the Food and Drug Administration (FDA), conducted research to learn more about scoring, grading, and placarding systems used by retail food regulatory programs in the United States.

In 2012, NACCHO surveyed local retail food regulatory programs to learn more about the implementation of scoring, grading, and placarding systems. NACCHO found that 38% of the respondents indicated that their jurisdiction provided retail food establishments with an overall grade, score, or placard after an inspection. Among the respondents that indicated they had a system, 75% used a numerical score; 16% used a letter grade; 10% used a color or other graphic to describe the inspection result; and 11% used another, unspecified type of system. (Percentages do not total 100 because respondents may have selected more than one choice.)

In addition, participants were asked to share their perception of the impact of their system. Among those respondents with a system, the survey found the following:

- 67% perceived that the system had no impact on how operators shared information during an inspection;
- 66% either agreed (52%) or strongly agreed (14%) that an assigned score or grade was correlated with an establishment's control of risk factors;
- 59% perceived that a scoring and grading system impacted how much attention operators paid to food safety; and
- 58% perceived that the system improved food safety.¹

NACCHO conducted four case studies from 2013 to 2015 to explore key questions about the implementation of scoring, grading, and placarding systems. NACCHO identified the retail food regulatory programs from the survey respondents. Information about the four participating retail food regulatory programs can be found in Table 1.

Through the case studies, NACCHO sought to explore the following questions:

- Why do retail food regulatory programs implement scoring, grading, or placarding systems? In other words, what purpose does a scoring, grading, or placarding system serve?
- How are stakeholders involved in the development and revision of scoring, grading, or placarding systems?

- How do jurisdictions derive point values and thresholds associated with scoring, grading, or placarding systems?
- How does the implementation of a scoring, grading, or placarding system impact a retail food regulatory program’s resources?
- How does the implementation of a scoring, grading, or placarding system impact behavior for consumers, regulators, and establishment operators?
- Have jurisdictions collected data on the impact of their scoring, grading, or placarding system? If so, does the data suggest that a particular approach has more, or less, of an impact on food safety?

Methods

NACCHO identified and selected potential case study participants from its 2012 survey. To obtain a broad perspective on scoring, grading, and placarding, survey respondents were grouped into three categories:

1. Jurisdictions where the respondent reported positively on all questions about the perceived impact on (1) overall impact on food safety (highly agree); (2) operational control over risk factors associated with operator behaviors (highly agree); and (3) all three operator behaviors (attention to food safety, communication with inspectors, and how inspections conducted).
2. Jurisdictions where the respondent reported mixed perceptions on the above questions.
3. Jurisdictions with characteristics that would bring further insight into scoring and grading systems such as a local jurisdiction implementing a state-mandated program.

The list of selected jurisdictions (see Table 1) includes a variety of Health and Human Services regions and a mixture of urban and rural sites. From 2013 to 2015, NACCHO conducted telephone interviews with key informants from each selected retail food regulatory program. Key informants included health department staff, board of health representatives, food establishment operators and owners, and food safety consultants.

TABLE 1
CHARACTERISTICS OF SELECTED SITES

Site	Geographic Characteristics	Other Characteristics
POSITIVE PERCEPTIONS OF IMPACT		
Southern Nevada Health District, Nevada	PHS Region 9 Population 2.1 million FDA Pacific Region	Very comprehensive system with letter and number reported on premises; received media coverage Grading system was implemented in 2010 or earlier
Kern County Public Health Department, California	PHS Region 9 Population 874,589 FDA Pacific Region	Grading system was implemented in 2010 or earlier Uses a score and grade posted on premises
MIXED/NON-POSITIVE PERCEPTIONS OF THE IMPACT		

Monmouth County Health Department, New Jersey	PHS Region 2 Jurisdiction, Population 352,000 FDA Central Region	State-based food safety placard system
Louisville Metro Department of Public Health and Wellness, Kentucky	PHS Region 4 City, Population 1.3 million FDA Central Region	Uses a score and grade posted on premises

Results

Why do retail food regulatory programs implement scoring, grading, or placarding systems?

Case study responses suggest that there are three primary reasons for implementing a scoring, grading, or placarding system. A single reason, or combination of reasons, may influence a jurisdiction’s decision to implement a scoring, grading, or placarding system. Retail food regulatory programs implement these systems for the following reasons:

1. They want to communicate a “snapshot” of information about the inspection results to the consumer.
2. They want to use information derived from the scheme to adjust inspection frequency or serve as a threshold for taking additional enforcement actions.
3. They want to incentivize retail food establishment operators to more rapidly correct problems and take a more proactive approach to preventing problems by publicly displaying scores, grades, or placards.

Overview of Participants’ Grading, Scoring, or Placarding Systems

The case study participants employ different scoring, grading, or placarding system. Table 2 provides an overview of the scoring, grading, or placarding system.

Table 2. Overview of Types of FISG Systems Used

Jurisdiction	What results are displayed after an inspection?	How are the overall inspection results determined?	How many points are assigned to each violation?	How did the jurisdiction determine how many points to assign to each violation?
Kern County Public Health Services Department, CA	Letter grades and placard color convey inspection results.	<p>“A” score and blue placard: 90 to 100 points</p> <p>“B” score and green placard: 80 to <90 points</p> <p>“C” score and yellow placard: 75 to <80 points</p> <p>Notice of Closure and red</p>	<ul style="list-style-type: none"> • 5 points for major risk factors • 3 points for minor risk factors • 3 points for other risk factors • 0.5 point for non-critical violations 	Borrowed and customized Los Angeles County’s and San Bernardino County’s policies to determine point values for each violation.

		placard: 0 to <75 points		
Louisville Metro Public Health and Wellness, KY	Letter grades and placard color convey inspection results.	<p>“A” grade (Green card): 85–100% and no critical violations were cited.</p> <p>“B” grade (Blue card): Failed 2 consecutive inspections prior to passing the most recent follow-up; failed a follow-up inspection; or was recently closed due to imminent public health violations, then re-inspected and opened after passing a follow-up inspection.</p> <p>C grade (Red card): Failed to meet minimum requirements of The Kentucky State Food Code upon the most recent inspection. This includes an inspection where one or more critical violations are observed.</p>	<ul style="list-style-type: none"> • 3–5 points for critical violations • 1–2 points for non-critical violations 	The state’s inspection form assigns point values for each violation. These point values are assigned to each violation when determining the numerical score.
Monmouth County Health Department, NJ	Inspection results are summarized by assigned categories	<p>“Satisfactory”: The establishment is found to be operating in substantial compliance with</p>	Not available	State inspection forms assign point values for each violation.

		<p>this chapter and food service personnel have demonstrated that they are aware of and are practicing sanitation and food safety principles as outlined in this chapter;</p> <p>“Conditionally satisfactory”: At the time of the inspection, the establishment was found to be out of compliance with one or more critical violations that were not corrected while the inspector is onsite; food service personnel were found to be improperly handling food; or an establishment committed a repeat violation.</p> <p>“Unsatisfactory”: Whenever a retail food establishment is operating in violation of this chapter, with one or more violations that constitute gross insanitary or unsafe</p>		
--	--	---	--	--

		<p>conditions, which pose an imminent health hazard, the health authority shall immediately request the person in charge to voluntarily cease operation until it is shown on re-inspection that conditions which warrant an unsatisfactory evaluation no longer exists.</p>		
<p>Southern Nevada Health District, NV</p>	<p>Letter grades and placard color convey inspection results</p>	<p>“A” grade (Blue card): 0 to 10 demerits on their last inspection.</p> <p>“B” grade (Green card): 11 to 20 demerits or identical consecutive critical or major violations.</p> <p>“C” grade (Red card): 21 to 40 demerits, has identical consecutive critical or major violations, or more than 10 demerits on a “B” grade re-inspection</p> <p>Notice of Closure (Pink card): 41 or more demerits,</p>	<ul style="list-style-type: none"> • 5 points for critical violations • 3 points for major violation • 0 points for good food management practice violations 	<p>Point values were initially assigned by the health department.</p> <p>Point values have evolved over time to increase the focus on foodborne illnesses risk factors.</p>

		an imminent health hazard requiring closure was cited, or failed a "C" grade re-inspection.		
--	--	---	--	--

How do jurisdictions derive point values or thresholds associated with scoring, grading, or placarding systems?

Participants derived point values or thresholds with the systems using various methods. Kern County used the California Retail Food Code and a report from the Centers for Disease Control and Prevention (CDC) to help associate risk factors to violations (e.g., major, minor, non-critical).² To determine point values for violations, Kern borrowed and modified from other local jurisdictions in California. Southern Nevada Health District created their own demerit and point value system that has evolved over time to focus directly on risk and contributing factors of foodborne illnesses. Louisville’s point values are based on the state inspection form, which assigns point values for each violation. The state inspection form uses the 2005 Food Code to determine which violations are critical or non-critical.³ Monmouth County uses the New Jersey state system. New Jersey’s inspection form is based on a form developed by the Conference for Food Protection.

How does the implementation of a scoring, grading, or placarding system impact a retail food regulatory program resources?

All participants stated that implementation of a scoring, grading, or placarding system requires extra resources and time. For example, health departments had to educate the food industry about the system. Participants indicated that their health departments expended resources to conduct training sessions, produce and disseminate fact sheets, mail information, and create online resources. Participants also provided information and trainings to the industry when revisions were made to their systems and regulations. For example, Southern Nevada conducted 25 informational sessions and trained over 8,000 industry members on an updated regulation in 2010. Local health departments also expended resources to educate their staff. Participants indicated that they incorporated the scoring, grading, or placarding policies into their inspector training program. All participants require their inspectors to be formally trained, take continuous education courses annually, and participate in ethics trainings. Kern, Louisville, and Southern Nevada stated that they utilized media outlets to inform and educate the public about the system.

Compliance and enforcement policies were incorporated into scoring, grading, or placarding systems. All the participating health departments required facilities to close or asked them to voluntarily close if they had imminent health hazard violations. As part of the scoring, grading, or placarding system, each jurisdiction also required establishments to close when they scored under a minimum score/grade. Re-inspection fees were a notable difference between the case study participants. Kern, Southern Nevada, and Monmouth charge a fee for re-inspection. Louisville charges annual permit fees that cover routine annual inspections but does not charge additional fees for re-inspections due to low scores, grades, or placards.

Appeals processes were also incorporated into scoring, grading, and placarding systems. Each case study participant provided a mechanism for facility operators to contest scores, grades, or ratings. Kern's and Louisville's appeals processes required operators to submit written requests to the health department. On the other hand, Monmouth and Southern Nevada Health District employed an informal process in which the establishment operator calls the department's supervisor. Each case study participant indicated that appeals for scores, grades, or placards were infrequently requested. For example, Kern and Louisville stated that they received less than one appeal per month due to low scores, grades, or placards.

How are inspection results, including grades, communicated to the public?

All participants required the retail food establishment to post the grade, score, or rating placards in a conspicuous location in their facility. In addition to the conspicuous posting of the score, grade, or placard, all participating health departments required facilities to provide the inspection summary reports to the consumer upon request. Each local health department also provided either full or partial inspection results on their website. In addition to the methods described above, other communication methods included posting Quick Response (QR) codes on their placards, mobile applications, and through local media outlets such as television shows, websites, and newspapers. In Louisville, the health department partnered with Yelp, a social media company, as one method to communicate inspections results to the public.

All participants stated that the local media regularly list the retail food establishments that receive low scores, grades, and ratings. Representatives from Southern Nevada and Kern have heard anecdotes, or perceive, that media coverage on scores and grades may impact consumer behavior, at least in the short term. None of the participants have data available to show the impact of the media coverage on the system and consumer behavior.

How are stakeholders involved in the development and implementation of scoring, grading, or placarding systems?

All systems, except for Kern's, were formed and implemented prior to when the interviewees began working at the health department. Kern's system was the result of an initiative by their Board of Supervisors to proactively create a food inspection scoring and grading system for Kern County. Although NACCHO was able to gather information about the formation and implementation of only Kern's policy, each health department involved members of the retail food industry in some way when revising their policies. In addition, Kern and New Jersey examined and borrowed elements from other jurisdictions' policies and systems when forming their systems.

The majority of the interviewees could not provide information about the barriers and facilitators to the systems' initial implementations. However, Kern identified their initial barrier as forming a policy that would satisfy economic growth and business development while promoting food safety. A Kern representative noted that a few industry members were wary of the motives behind the system. The Louisville representative stated that staff buy-in to the system is a constant battle and they address the issue by involving the staff when revising the system. The Southern Nevada representative stated that heavy staff workload is a constant barrier to their system and inspection program, while the representative from the State of New Jersey Department of Health believed that there are no barriers specific to its system because it has been in place for many years.

Controversy was reported for some of the scoring, grading, or placarding systems. In Southern Nevada, the industry representative stated that some industry members were concerned that the grade misrepresented their facilities' operations because inspections only represent a "snapshot" of their overall operations. In Kern, industry representatives were initially concerned with the fairness of the system for poor-performing operators compared to strong-performing operators. The poor performers would be required to make more adjustments than the strong performers to be successful within the new system; thus, poor performers were more likely to be negatively impacted by consequences of the policy such as loss of customers after receiving a low grade.

How does the implementation of a scoring, grading, or placarding system impact behavior for consumers, regulators, and establishment operators?

The systems impacted the nature of the inspections and relationship between inspectors and operators in different ways among the participating jurisdictions. For example, the Southern Nevada Health District's representative believed that their system provides incentives for retail food facility operators to fix violations quickly. In Louisville, a representative noted that a small number of inspectors found the system stressful because it was their responsibility to post the grades in highly visible areas of the facilities. Representatives from both Monmouth and Kern did not think their systems impacted the way inspections are conducted. However, Monmouth believed that if they switched from a placard system to a scoring or grading system, then their inspections would be negatively impacted. For example if an establishment received a low score (i.e. less than 70), the owners/operators may feel more threatened than they would if they received the "Conditional Rating" because it is common public perception to associate a score less than 70 as failing. Owners/operators that feel threatened are often more adversarial and this limits the opportunities that inspectors have to explain correct food safety practices and effect meaningful behavioral and procedural changes

The majority of the participants believe that having a system has increased consumer awareness of retail food inspections and inspection results. Representatives from Kern and Southern Nevada stated that their systems increase consumer awareness because grades are more relatable to the public than jargon or terms that are often found in inspection reports. In addition, Kern's industry representatives stated that they believe that the grades impact consumer's dining decisions. In Louisville, the opportunity to increase consumer awareness of retail food inspection results grew when the health department went from having no communication of inspection results to the public to having inspection results communicated through placards, its website, a mobile app, and Yelp.

Have jurisdictions collected data on the impact of their scoring, grading, or placarding system? If so, does the data suggest that a particular approach is more effective?

Case study participants reported that they have not analyzed data to assess their system's impact on retail food establishment practices or foodborne illness in the community. Southern Nevada Health District has not analyzed data because of the difficulty in measuring the prevention of foodborne illness. Kern and Louisville health departments plan to collect and analyze data in the future. Anecdotally, the Kern representative has heard from retail food establishment operators, employees, and inspectors, that their system has a positive impact on retail food establishment practices. In addition,

Louisville’s representative believes that there is at least a perception that their system positively impacts food safety because their system incentivizes operators to eliminate foodborne illness risk factors by rewarding them with an “A” grade.

The majority of the participants have revised their system since it was first implemented. Only New Jersey has not and does not plan to revise their placard system. However, New Jersey worked with the industry to explore other systems such as letter grades. Industry objected to the proposed change because the system may be negatively influenced by inconsistent practices among inspectors. All other participants included industry members as part of their advisory groups when revising their systems. Louisville and Southern Nevada stated that they have revised their system throughout the years to focus more on foodborne illness risk factors.

Recommendation on Forming and Implementing Scoring, Grading, or Placarding System

All participants recommended that health departments base their retail food inspection programs on foodborne illness risk factors. For health departments interested in scoring, grading, or placarding systems, participants recommended the following:

- Provide a formal and transparent process for stakeholders (i.e., industry members and health department staff) to provide input when developing, reviewing, and updating policy and processes;
- Incorporate a formal process for the food industry to appeal scores, grades, or placards; and
- Provide education and training to all inspectors and supervisors on the system.

References

1. National Association of County and City Health Officials. (2014). *Study of Retail Food Establishment Inspection Scoring and Grading Systems* [research brief]. Retrieved June 3, 2016, from <http://eweb.naccho.org/prd/?NA617PDF>
2. Olsen, S. J., MacKinnon, L. C., Goulding, J. S., Bean, N. H., & Slutsker, L. (2000). Surveillance for foodborne-disease outbreaks—United States, 1993–1997. *Morbidity and Mortality Weekly Report*, 49 (SS01);1-51
3. Food and Drug Administration. (2005). Food Code 2005. Retrieved June 3, 2016 from <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm2016793.htm>

Acknowledgments

This document was made possible through support from the Food and Drug Administration, cooperative agreement #5U50FD004334-04. NACCHO is grateful for this support. The views expressed within do not necessarily represent those of the sponsor.

For more information, please contact:

Amy Chang, MS
Program Analyst, Environmental Health
202-507-4221
achang@naccho.org

Jennifer Li, MHS
Senior Director
Environmental Health and Disability
202-507-4242
jli@naccho.org

“Co-Relation of Sate Pharmacy Acts with State Drug Laws”

Sylvester H. Dretzka

Secretary, State Board of Pharmacy of Wisconsin

Presented at the Forty-Fifth Annual Conference, St. Paul, MN, June, 1941

The extent of cooperation between State Boards of Pharmacy and State Drug Departments varies with the divergence of the State Acts study of which discloses that few are identical. Such a situation calls for a broad framework of policy which will permit both Boards and Departments to operate within this framework quite freely without restraint.

Speaking quite generally, out States may be divided into “haves” and “have nots”: those which have passed State Acts paralleling that of the New Federal Act and those which have not. The “have nots” are further divided into those who tried to pass an act and failed and those who chose to wait. Also, there is a twilight zone group of States who made an attempt to gain such legislative approval and failing, chose to effect some changes in existing State Acts so as to gain something while waiting. Wisconsin is in the latter group. When it appeared that legislative approval was not forthcoming, it was decided to make some changes in existing statutes, and we felt that all have profited thereby. It was necessary to have the approval and cooperation of the other State departments to effect these changes. It was also felt that our Pharmacy Act was more in need of modernizing than the Food Laws, as the latter already had many excellent provisions.

In addressing a national group such as this upon the topic of the co-relation of state pharmacy acts with state drug laws, there will be all possible variations of opinion as to the need and desirability of such co-relation. In some of our states, there is a close relationship between these two phases of legislation; in others there is none whatever. Out of this discussion it is hoped that a more uniform procedure may develop and that the true test of such activity can be applied, namely that of protecting the health of the American public. From the historical standpoint, it is easy to see why in some states there is inadequate co-relation between the two groups. Most state pharmacy acts have grown out of the Professional Practice Acts where the pharmacists of the state have had enacted laws regulating the practice of pharmacy from the standpoint of who may become a pharmacist, the educational requirements, and the conduct of the profession. While in some cases, the statutes included as part of the act the pure drug qualifications, the enforcement of these later sections was often inadequately provided for. This, in many cases, had led to the unfortunate condition where there is little or no attempt to control the quality of the drugs used as medicines. On the other hand, in many of the states, the pure drug section of the statutes has been entrusted to the Department of Agriculture along with the Pure Food sections. The pharmacist has no quarrel with the placing of the food unit; it is the drug section he feels belongs to him.

Because of the lack of previous co-relation between the two groups, it is hoped that out of a discussion such as this, a new concept of the subject may result. That there is need for more adequate and complete drug sections in the individual state law is well known. The change can be brought about only by meeting on a common ground.

Specifically, then the methods for obtaining the desired co-relation call for close cooperation between the drug control officials in each state and the pharmaceutical group. Only by full understanding on the part of the two groups, however, will there ever be adequate cooperation. The pharmacists must be brought to the realization that the dispensing of pure drugs is an essential part of their responsibilities, and that from the ethical and moral standpoint they should cooperate in the passing of an adequate state drug law. By bringing these facts to their attention the passage of a satisfactory law will be much easier.

Your invitation gives me an opportunity to tell you how certain features of the New Federal Act and others were incorporated into our Pharmacy Act when, in 1939, it became evident that a parallel state act would fail to pass. Following are some of the changes which were secured and which have proved helpful:

- A. The Federal definition of "drugs" was adopted.
- B. Our Board was empowered to make rules and regulations.
- C. The Board was empowered to employ additional inspectors, special investigators, chemists, agents, and clerical help.
- D. The Board was empowered to hold hearings and revoke licenses:
 - 1. For repeated violations of the Pharmacy Act of its Rules and Regulations.
 - 2. For repeated acts of unprofessional conduct, including adulteration and substitution.
- E. The Board officers were empowered to issue subpoenas and administer oaths.
- F. Labeling of Patent and Proprietary Medicines was required to conform to the Federal Law as well as the State Law.
- G. The sanitary inspection of prescription rooms was authorized.
- H. Manufacturers of medicinal products were required to be licensed and to employ professional personnel.
- I. The Board of Pharmacy and the Board of Health were given concurrent authority in enforcing the provisions of the State Law on poisons and narcotics.
- J. Penalties were increased and violations made criminal, instead of civil, offenses.

It is to the credit of Wisconsin pharmacists that finding the enactment of a uniform Food, Drug, and Cosmetic Act unlikely they secured the above provisions. Furthermore, almost the entire enforcement program is paid for by the pharmacists themselves through the payment of annual fees to the State Treasury. The pharmacists of our state have never yet received a state appropriation but on the other hand have, during times of stress, replenished the General State Fund.

While this statement on finances may not seem to apply to the subject matter of this paper, I emphasize it here because a similar condition is found in many other states. I wish to point this out as a means to facilitate adoption of uniform state acts in such states where finances seem to be a deterrent to such passage. Let us assume that the Department Agriculture in our state did not have an appropriation sufficient to properly

enforce its provisions. Under the arrangement which obtains in our State, the Board of Pharmacy assumes much of this enforcement responsibility under its own financing.

It is to the credit of our Department of Agriculture that its administrators cooperated wholeheartedly in strengthening our Statute. The philosophy of that department can best be summed up by the comments of its administrators:

MR. RALPH AMMON (*Department Director*): "We must have a free interchange of ideas and information."

MR. L. G. KUENING (*Chief, Dairy Division*): "Sharing of information is essential so that double pressure may be brought on violators."

MR. R. R. CROSBY (*Chief, Food Section*): "The things that are different in our departments may be the things that are most helpful."

Our work is more directly with Mr. Crosby, but it has the wholehearted approval of his two above name superiors. We confer frequently and begin by exacting Federal compliance of all products submitted for checking.

In addition to the above, I believe observance of the following in each state would do much to co-relate the work of our Pharmacy Boards and Drug Departments:

1. Definitions for the terms "drugs," "cosmetic" and other terms used in both Food, Drug and Cosmetic Acts and Pharmacy Acts should coincide.
2. Regulations with respect to the control of drugs, cosmetics and devices as covered by both Pharmacy and Food and Drug Acts should coincide.
3. Enforcement activities in the control of the manufacture and distribution of drugs, cosmetics and devices should be coordinated as much as possible.
4. There should be complete and active cooperation between the Federal Food and Drug Administration and State enforcement agencies.
5. There should be greater appreciation on the part of the Food and Drug officials who are active in the enforcement of the drug, cosmetic and device provisions of the Federal and State Food, Drug and Cosmetic Acts of the necessity for restricting the sale of drugs to qualified pharmacists. Too often the attitude of the food and drug official is that, if the product is not adulterated or misbranded, it makes no difference by whom it is sold. The fact is that it does make a difference. A general merchant is not in a position to interpret drug labels or even to understand them and there is no control over the general merchant from a professional point of view. When a pharmacist violates the law, he is not only subject to a penalty for such violation but he is also in danger of losing his right to practice through suspension revocation of his certificate of registration. This is a very formidable club and receives much greater consideration on the part of the distributor if he is a pharmacist than does the customary penalty for violation of the law.

It is important to emphasize the need for information from the Food and Drug Administration at Washington. For example, when the Administration decides that certain rugs should be classified as dangerous and cannot be properly labeled for use without a physician's advice, uniform lists of such drugs should be supplied to all state

enforcement agencies. This has been done recently but until it was done there was great uncertainty as to what constitutes "dangerous drugs."

It does not help drug law enforcement nor does it improve the attitude of those affected if one state enforcement agency supplies information which differs from the information supplied by another in so important a matter as the restriction of sales or drugs to physician's prescriptions. If we are going to have uniformity of enforcement and uniform compliance, we must have uniform regulatory procedures, and we must all have the information at the same time. The only way this can be done satisfactorily is by the establishment of a definite procedure for the prompt and complete dissemination of information from a competent source; namely the Food and Drug Administration at Washington, D.C., which must necessarily take the lead in these matters.

In connection with the distribution of new drugs, it becomes particularly important that state enforcement agencies are kept informed as to what drugs may be considered as safe for distribution either on a physicians' prescriptions or otherwise. Unless the Food and Drug Administration arranges to supply state enforcement agencies with information as to the status of various drugs for which application is made, we shall have a condition where Federal compliance may be achieved but liberties may be taken with the distribution of drugs in the several states when such drugs may be actually dangerous.

I would urge an early understanding between the Food and Drug Administration and state enforcement officials with respect to the dissemination of information on New Drug Applications from the Food and Drug Administration.

In passing the Federal Food Act, cooperation of Congress was secured on the basis of the public health factor. The pharmaceutical profession cooperated on the same basis. It is now found that the short phrase "to be sold by or on the prescription of a physician" can and is being abused by many dispensing physicians to such an extent that it carries no public protection. There are instances of pharmacists refusing to sell old customers a dangerous drug and who find later that it was dispensed by neither a pharmacist nor a physician when the patient visited the office of his family physician, the dispensing being done by an office girl.

If the states that have not as yet passed a parallel act are to be solicited for cooperation, I urge the inclusion of the pharmaceutical viewpoint which may do away with these inequalities by providing for the dispensing of drugs by physicians in emergency quantities only. In this we will have the hearty cooperation of the outstanding medical practitioners.

Coordination of Federal and State Project Plans: State Participation

**V.L. Fuqua, Superintendent, Division of Foods,
State Dept. of Agriculture, Tennessee**

Presented at the Forty-Fifth Annual Conference, St. Paul, Minn., June, 1941

It is my belief that all States can participate in the "Coordination of Federal and State Project Plans" to the extent of the scope of their laws, financial backing and the energy and willingness of the State Official. The Federal Food and Drug Department has shown an excellent spirit of cooperation by the holding of meetings with State Officials in given localities where problems are somewhat uniform, and has outlined in detail their plans for the coming year, discussing in detail the various ramifications, outlined time of the year for particular work and has asked our assistance in carrying the program through. What more could we ask? It has certainly shown that they are not trying to replace the State Governments or Agencies as some Federal Agencies have been accused of attempting. It shows that they are not only trying to help us in our problems but at the same time they are asking our help in solving some of their problems.

The Federal Food and Drug Administration has its limitations as to jurisdiction and some concerns realizing this have resorted to various practices based on eliminating the possibility of allowing some of their products in interstate commerce. I believe that we as State Officials should work on these local products in conjunction with and at the same time similar work is being done by the Federal Department on similar products insofar as possible. By working along this line I have found that rapid results are obtained. This was particularly true with the candy industry in our State. The sanitary conditions of some plants in the State were deplorable, some of the plants were doing an intrastate business only, some were operating in interstate. Thorough inspections were made of both types of plants in conjunction with Federal inspectors, both types of operators being issued similar orders for the elimination of these insanitary conditions. Some cleaned up completely, others only partially and two made no attempt to place their house in order. These two were prosecuted in Federal court and the effect on all of the others was astounding. Even those that were satisfactory entered into a campaign of repainting and some other work that was really not needed.

There has been a different attitude expressed by all operators in the State. They realize that it doesn't make any difference as to whether they do business in intrastate or in interstate, that they will be treated alike and furthermore that we were working hand in hand with the Federal Authorities on the same projects at the same time and that they can't hide behind a smoke screen of politics. We had known for some time about the conditions that were existing in the two plants referred to as being prosecuted but we also knew that as they were located in Memphis that we could not expect to get a conviction if we took them to court consequently we had been bluffing along, but this is over now; the word has passed from one end of the State to the other that if you do not cooperate with the State Department you had better look out for a double drive from both the Federal and State Departments and furthermore that they will each back the other and that their methods of inspection and action are uniform.

Participation through cooperation and understanding, we have found to be of tremendous assistance. We enjoy participating in programs of the Federal Agency. There is a certain satisfaction in knowing that everybody is working together, that at the same time you are correcting some evils in your State that the same thing is being corrected throughout an entire area. There is strength in unity and some concerns cannot go to another similar concern located in another locality and cry on their shoulder about how they are being persecuted when if they were only located in another state or were only doing an intrastate business they would be scott free.

Participation with, entails understanding of the Federal program, unification of purpose, and action. Without understanding the plans and projects, we cannot participate. Without unification of purpose we cannot participate. Without unification of action we cannot participate. Regulatory work is like a chain, if one link is weak that is where trouble begins; the chain cannot be stronger than its weakest link and the Sates are definitely a link in the regulatory chain Unless Sates cooperate with and participate in the Federal program, I sincerely believe that the States will be the ones to suffer the greatest damage as we will lose the respect of our local constituents in addition to losing the vast amount of help that can be given by the experience and facilities of the Federal Agency.

I am sure that it is the intention of every delegate from the States attending this Convention to cooperate to the fullest extent with the Federal Agency and that we will not fail in our efforts as "Failure is the Only Thing that Can Be Achieved Without Effort

Mark Your Calendar

With these important dates:

CASA Educational Conference

May 1-4, 2017

Saratoga Springs, NY

Food Safety Summit

May 9 - 12, 2017

Chicago, IL

NEFDOA

May 17 - 19, 2017

Providence, RI

AFDO 121st Annual Educational Conference

Hosted by MCAFDO

June 17 - 21, 2017

Houston, TX

J **JOURNAL**

ASSOCIATION OF FOOD AND DRUG OFFICIALS

2550 KINGSTON ROAD, SUITE 311, YORK, PA 17402

NON-PROFIT ORG
U S POSTAGE
PAID
YORK PA
PERMIT #200