

JOURNAL
of the
ASSOCIATION OF FOOD AND DRUG OFFICIALS

Proceedings Issue

June 2004

Serving the regulatory community since January 1937

CONTENTS OF THIS ISSUE

FROM THE EDITOR	1
ABOUT THE AUTHORS	3
FDA KEYNOTE	6
CANADIAN KEYNOTE	15
GLENN W. KILPATRICK MEMORIAL ADDRESS	25
PRESIDENTIAL ADDRESS	29
PRESIDENTIAL PROCEEDINGS	34
PRESENTATION OF ASSOCIATION AWARDS	36
CONSTITUTION AND BYLAW AMENDMENTS	38
2004 RESOLUTIONS	40
MINUTES OF THE BOARD OF DIRECTORS' MEETINGS	50
2004 BUSINESS MEETING MINUTES	75
2003-2004 ADOPTED MODEL CODES AND GUIDELINES	76
FINANCIAL REPORT	77
2004-2005 FINAL COMMITTEE REPORTS	78
2004-2005 COMMITTEE CHARGES	79

ASSOCIATION OF FOOD AND DRUG OFFICIALS

Mission Statement

The Association of Food and Drug Officials (AFDO), established in 1896, successfully fosters uniformity in the adoption and enforcement of science-based food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO and its six regional affiliates provide the mechanism and the forum where regional, national and international issues are deliberated and resolved to uniformly provide the best public health and consumer protection in the most expeditious and cost effective manner.

OFFICERS

- * President Cameron Smoak, Atlanta, GA
- * President-Elect..... Marion Aller, Tallahassee, FL
- * Vice-President Charlene Bruce, Jackson, MS
- * Secretary-Treasurer John Lattimore, Austin, TX

DIRECTORS

Elected *Steve Steingart (2008).....Pittsburgh, PA
at Large James Waddell (2005).....Sacramento, CA

Elected by Al Ondis (2008)..... Central States
Affiliated * Denis Blank (2005)..... Mid Continental States
Regional * William Krueger (2005).....North Central States
Associations Paul Tierney (2008)..... North Eastern States
R. Douglas Saunders (2005)..... Southern States
Barbara Hruska (2008) Western States

BOARD * Past President.....Chris Wogee, Sacramento, CA
RESOURCES * Director of Public PolicyJoseph Corby, Albany, NY
AND * Canadian Advisor Colin Broughton, Toronto, Canada
SUPPORT * CDC AdvisorArthur Liang, Atlanta, GA
* FDA Advisor Richard Barnes, Rockville, MD
Special Advisor..... Betsy Woodward, Tallahassee, FL
* USDA Advisor..... Ralph Stafko, Washington, DC
DHS Advisor John Hoffman, Raleigh, NC
Journal Editor Thomas (Bill) Brooks, Columbia, SC

OFFICE * Denise Rooney, Executive Director
Leigh Ann Stambaugh, Administrative/Special Projects Assistant
Shirl Bortner, Assistant to the Executive Director
Diane Rooney, Support Staff

Address 2550 Kingston Road, Suite 311, York, PA 17402
Phone Voice (717) 757-2888 / Fax (717) 755-8089
Email afdo@afdo.org
Internet http://www.afdo.org

*Member of Executive Committee

FROM THE EDITOR

Our annual Education Conference is behind us now. For those who were not able to attend, this proceedings issue of our Journal will provide you with a glimpse of what went on in Pittsburgh. Those of us who were able to be there enjoyed a generous helping of useful information and the rejuvenating effect of fellowship with our peers in food and drug regulatory work.

While we cannot capture all of the business and presentations that made up the three-and-a-half days of the conference, what we have in this issue of our Journal should give you a flavor of the event. The range of subjects and issues presented to us in Pittsburgh covered most of today's concerns for consumer protection including food safety and security, health fraud, nutritional supplements, bioterrorism legislation and the national uniformity issue. Perhaps in a future issue we will be able to bring you conference presentations we were not able to capture for this issue.

Thomas W. (Bill) Brooks, Editor

AFDO JOURNAL EDITORIAL BOARD

AFDO Journal National Editorial Coordinator

Bill Brooks, Ph.D. AFDO Journal Editor **Phone** (803) 737-9700
SC Dept. of Agriculture **FAX** (803) 737-9703
PO Box 11280 **Email** bbrooks@scda.sc.gov
Columbia, SC 29211

AFDOSS Journal Editorial Board Representative

Laurie Farmer FDA **Phone** (404) 253-1175
60 Eighth Street, NE **FAX** (404) 253-1207
Atlanta, GA 30309 **Email** Laurie.Farmer@fda.gov

Associate Journal Editorial Board Representative

Maury Bandurraga, Procter & Gamble **Phone** (513) 622-1672
Ph.D. 8700 Mason-Montgomery **FAX** (513) 622-0558
Box 589 **Email** bandurraga.mm@pg.com
Mason, OH 45040

CASA Journal Editorial Board Representative

Kenneth Hohe 4731 Count Street **Phone** (717) 652-5325
Harrisburg, PA 17109 **FAX** (717) 652-1533
Email kenhohe@aol.com

MCA Journal Editorial Board Representative

Dan Sowards TX Dept. of Health **Phone** (512) 719-0243
2600 Monitor Drive **FAX** (512) 719-0263
Austin, TX 78745 **Email** dan.sowards@tdh.state.tx.us

NCAFD Journal Editorial Board Representative

Vacant

NEFDOA Journal Editorial Board Representative

Frank Greene CT Dept. of Consumer **Phone** (860) 713-6160
Protection **FAX** (860) 713-7237
165 Capitol Ave. Rm. 165 **Email** Frank.Greene@po.state.ct.us
Hartford, CT 06106

WAFDO Journal Editorial Board Representative

Mary Ellen Taylor FDA **Phone** (510) 337-6888
1431 Harbor Bay Parkway **FAX** (510) 337-6708
Alameda, CA 94502 **Email** mtaylor1@ora.fda.gov

ABOUT THE AUTHORS

Dr. Lester M. Crawford received his Doctor of Veterinary Medicine (DVM) from Auburn University, his PhD in pharmacology from the University of Georgia, and his Honorary Doctorate (MDV) from Budapest University of Veterinary Science.

Dr. Crawford has held significant positions in the academic and professional worlds throughout his career. These include: Director of FDA's Center for Veterinary Medicine from 1978-1980 and 1982-1985, Head of the University of Georgia's College of Veterinary Medicine Department of Physiology-Pharmacology from 1980-1982, Administrator of USDA's Food Safety and Inspection Service from 1987-1991, Executive Vice President-Scientific Affairs of the National Food Processors Association from 1991-1993, Executive Director of the Association of American Veterinary Medical Colleges from 1993-1997, Director of the Center for Food and Nutrition Policy from 1997-2002, Acting FDA Commissioner from February through November 2002, and FDA Deputy Commissioner from November 2002-March 2004.

As the current Acting Commissioner of the FDA, the nation's principal consumer protection agency, Dr. Crawford ensures the safety and protection of the public's health. Health and Human Services Secretary Tommy Thompson has said, "Lester Crawford has devoted his career to promoting safer products for the public, and he brings to the FDA valuable experience and leadership skills. With his help, the FDA will continue to build on its successes in ensuring the safety of foods, drugs, and medical products for all Americans."

Dr. Crawford has played major roles in mandatory nutrition labeling, the formation of the World Trade Organization and the control of chemical and microbiological contaminants of food. He has been an advisor to the World Health Organization and the Food and Agriculture Organization of the United Nations for much of his career.

Dr. Crawford is a Member of the National Academy of Sciences -- Institute of Medicine. He is a Fellow of the Royal Society of Medicine (UK) and a Fellow of the International Society of Food Science and Technology. In 1984, he was inducted into the French Academy of Veterinary Medicine. In 1991, he received the Wooldridge Award, the British Veterinary Association's highest award.

He has held lectureships of various kinds at a number of universities in the United States and abroad. These include: University of Porto (Portugal); Jordan University of Science and Technology; Berlin Free University; and Dublin Institute of Technology. University of Texas-San Antonio; Penn State University;

4 Association of Food and Drug Officials

University of Massachusetts; University of Wisconsin; University of California-Davis; Texas A&M; Virginia Tech; and Georgetown University.

He has been married since 1963 to Catherine Walker of Birmingham, Alabama. They have two daughters, Leigh and Mary, and four grandchildren.

Diane Gorman was appointed Assistant Deputy Minister of the Health Products and Food Branch on July 1, 2000. The Health Products and Food Branch takes an integrated approach to the management of the risks and benefits to health, related to health products and food. This is achieved by minimizing health risk factors to Canadians while maximizing the safety of the regulatory system for health products and food, promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

Prior to this appointment, Diane was Associate Assistant Deputy Minister of the Health Protection Branch of Health Canada. Diane came to Health Canada in April 1998 as Regional Director General for the Western Region, responsible for all of Health Canada's programs in the provinces of British Columbia and Alberta, as well as in the three northern Territories: Yukon, Northwest Territories and Nunavut.

Prior to joining Health Canada, Diane held the position of Assistant Secretary on the federal Treasury Board. In this capacity, she was responsible for a number of key reforms to the Human Resources management systems of the federal Public Service, including pay equity negotiations, creation of a universal job evaluation plan, and developing compensation plans for federal executives and for the military in National Defence and the RCMP.

Over her career, Diane has held senior positions in a number of federal departments, including Environment Canada, Supply and Services Canada, Secretary of State, Multiculturalism and Citizenship Canada, and Heritage Canada.

Diane has served as a Director of the Fraser Basin Council (British Columbia), as well as a member of the Mackenzie River Basin Board, an intergovernmental Board focusing on environmental issues, and on the Nova Scotia, Pacific and Alberta Councils of senior federal officials.

Dr. Colin Broughton, Ph.D., was educated to the doctorate level in analytical chemistry in the United Kingdom and then spent six years in analytical chemistry research in the pharmaceutical industry there.

In 1969 he was recruited by Health Canada to create a national pharmaceutical drug testing program. He was subsequently appointed Regional Director, Atlantic Region, responsible for all Health Protection Branch programs throughout Canada's four Atlantic Provinces.

He is currently the Regional Director of the Ontario & Nunavut Region of the Health Products and Food Branch at Health Canada. His program responsibilities there include the safety of pharmaceutical drugs (both prescription and over-the-counter), medical devices, natural health products (dietary supplements in the USA), veterinary drugs, blood, blood products, tissues, organs, xenographic transplantation products and semen banks.

Dr. Broughton is based in Toronto and enjoys teaching downhill skiing, playing tennis and scuba diving in warm climates.

FDA KEYNOTE¹

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of the FDA

Good morning, and thank you for the kind introduction. I'm very pleased to be here, and I want to thank AFDO for hosting such an important dialogue on current challenges and opportunities impacting the public health.

It appears you have quite a power-packed schedule today (five keynotes, including mine), and I know you're going to enjoy hearing from my colleagues Diane Gorman from Health Canada and Ernesto Rubio from Mexico, as well as from USDA and CDC.

As today's schedule illustrates, advancing the public health is truly a collaborative effort that brings together many different organizations and agencies from around the world.

AFDO is an essential piece of this collaborative effort. You bring together government, industry and consumers both here in the U.S. and worldwide to discuss and debate important public health topics and figure out how to address them in the most effective and efficient manner. I'd like to thank you for all of your support of our various initiatives at FDA, and for your commitment to advancing America's health.

COMBATING BIOTERRORISM

Nowhere is this kind of collaboration more essential than in the area of counterterrorism.

In the wake of 9/11, Americans face new and sophisticated bioterror threats. In particular, our food supply has been widely recognized as a potential terrorist target: it is a life-sustaining, universally-consumed commodity; it is susceptible to contamination; and a significant amount of it — up to 80% of our seafood, and 20% of fresh produce — is imported from countries where we have no security presence.

Based on these considerations, the FDA was granted by Congress the lead responsibility for a broad-based, multifaceted program to protect the security of our food supply. We are currently implementing a number of unprecedented

¹ This text contains Dr. Crawford's prepared remarks. It should be used with the understanding that some material may have been added or deleted during actual delivery.

counterterrorism initiatives, with a heavy infusion of resources, and in close cooperation with an entire spectrum of federal, state, local and international agencies.

New Food Security Regulations

Specifically, FDA has implemented four new food security regulations to significantly extend our ability to prevent and respond to food safety threats:

- Prior Notice of Imported Foods
- Registration of Food Facilities
- Administrative Detention
- Establishment and Maintenance of Records (final rule upcoming)

These new rules represent innovative solutions to 21st century problems. They offer us comprehensive new information on food production and distribution for the first time, including a complete inventory of all food facilities both foreign and domestic, comprehensive information on all imported foods, and information on precisely who is handling food throughout the entire chain of custody on either side of the border. Through their cross-border “life cycle”-based approach, these new rules allow FDA to better identify potentially dangerous foods, as well as respond quicker to new threats and handle ongoing outbreaks more efficiently.

Since the Bioterrorism Act was passed, our agency has done a herculean job implementing it. We’ve set up Internet-based programs where firms can register and send, round-the-clock, prior notices of intended imports. We’ve developed the necessary rules and guidances, and conducted extensive outreach to explain the Bioterrorism Act to food exporters in Canada, Mexico, South America, and elsewhere around the world. We’re working closely with U.S. Customs and Border Protection (CBP) to design and implement these new regulations. We’re also working with Canada and Mexico on food security systems and infrastructure at both borders.

By the end of this summer, this in-depth, comprehensive protective system will be fully in place and functioning.

The essential backbone and muscle of these new provisions are rooted in new resources and authorities granted to our agency by the U.S. Congress.

Within a few months of 9/11, Congress authorized a \$195 million supplemental appropriation for the recruitment of 655 new FDA Field employees, the great majority of whom are safeguarding our food. Three hundred of these new staffers are now posted at 90 major United States ports of entry, 33 are criminal

investigators, and 100 are chemists and analysts who have been added to the existing network of food-safety labs, plus a new Food Emergency Response Network. At present, 72 state and federal laboratories have submitted laboratory qualification checklists for membership in FERN.

FERN

I'd like to take a few moments to tell you more about this Food Emergency Response Network, or FERN as we call it.

FERN is a national initiative designed to integrate America's laboratory infrastructure in order to better detect and respond to bioterror threat agents at the local, state, and federal levels. The primary objectives of the FERN are fourfold:

1. Prevention (federal and state surveillance sampling programs to monitor the food supply)
2. Preparedness (strengthen laboratory capacity and capabilities)
3. Response (surge capacity to handle terrorist attacks or a national emergency involving the food supply), and
4. Recovery (support recalls, seizures, and disposal of contaminated food to restore confidence in the food supply).

FERN offers a tiered screening and confirmation testing laboratory system composed of federal, state, and local governmental laboratories. In particular, this network is responsible for analyzing food samples implicated in threats, terrorist events, or contamination, responding to large-scale emergencies involving food, and conducting ongoing programs to monitor food for the presence of threat agents.

The FERN initiative was begun at the behest of the White House Homeland Security Council and Interagency Food Working Group, and both FDA and USDA's Food Safety and Inspection Service (FSIS) have been directed to lead this effort. FERN's role in protection of the nation's food supply was further outlined in the Homeland Security Presidential Directive 9 (HSPD-9).

I'd like to emphasize here that the success of FERN relies on full collaboration and participation at not just the federal level, but also importantly at the state and local levels. And so, we are requesting ongoing cooperation and support through state laboratory officials' participation with our federal partners in the formation, development, and operation of the FERN.

A variety of committees and workgroups have already been formed. These include the FERN Steering Committee as well as other committees dealing with

analytical methods, surveillance, proficiency testing, training, and communications. State and federal participants of these groups will assist in the development of FERN policies and operating guidelines, participate in conference calls, and attend conferences and planning meetings.

State participants of the FERN include agricultural, public health, veterinary diagnostic, and environmental laboratories. Laboratories from a variety of federal agencies are also members of the FERN Steering Committee. These laboratories represent the FDA, FSIS, the Environmental Protection Agency, the Department of Defense, Bureau of Customs and Border Protection, the Agricultural Marketing Service, and the Animal and Plant Health Inspection Service. Other federal members of the FERN include the Federal Bureau of Investigation, the Department of Homeland Security, and the Centers for Disease Control and Prevention. In addition, the FERN is working closely with the Laboratory Response Network (LRN) and the National Animal Health Laboratory Network (NAHLN) to ensure there are no gaps in our nation's safety net for human health.

This is an ambitious effort, but it is an important one. And we hope we can count on your support of this strategic initiative by allowing your employees to work with us to bring it to completion. Your support of the FERN and its mission is vital for protecting our nation's food supply. I'd like to thank you in advance for your assistance and I look forward to our close collaboration in the months ahead.

In addition to our new food security regulations and the FERN initiative, FDA has taken a number of other important steps to combat bioterrorism. For example, we've issued guidances on security measures for every major type of food business and facility, both domestic and foreign. We initiated a scientific assessment of the vulnerability of our food to attacks with biological, chemical, and radiological agents. We've participated in interagency counterterrorism exercises; developed a rapid food-pathogen detector, carried out hundreds of inspections of food facilities based on appraisal of their vulnerability to terrorism, and we've multiplied many times over spot inspections of imported food products.

We're spending \$5 million working with the National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, and National Center for Natural Products Research on research in three broad food and animal feed security areas. All told, we have more than 25 intramural research projects on food security.

All this does not mean that we've eliminated the possibility of a terrorist attack on our food supply. But I'm happy to say we are far, far better prepared to prevent, mitigate, or cope with it than we were three years ago.

Medical Countermeasures / Project BioShield

Protecting consumers against terrorism and emerging disease also requires that Americans have access to safe and effective medical countermeasures. To that end, over the past year, FDA has worked closely with scientists and product developers and has taken new steps to speed the development of these safe, effective treatments.

For example, FDA collaborated with CDC and other sister agencies on the development and distribution of anthrax and smallpox vaccines. The agency also issued an important new guidance on the development of Radiogardase (“Prussian Blue”) for treatment of internal contamination with thallium or radioactive cesium.

FDA has also encouraged the development of new medical countermeasures through our support for the Project BioShield Act of 2004. This legislation was introduced to address the existing lack of reward for developing safer, more effective countermeasures. If/when it gets signed into law, BioShield will give FDA the authority to make new medical countermeasures available more quickly in the event of a terrorist attack.

This legislation has cleared the Senate and is currently awaiting action in the House. We are optimistic that Congress will soon finalize its work on this and send the BioShield legislation to the President for his signature.

GOOD MANUFACTURING PRACTICES

I’d like to spend the rest of my time this morning discussing some important steps FDA is taking to improve the safety and efficacy of the products we regulate by updating the way these products are manufactured. What we’re talking about here are the so-called Good Manufacturing Practices, or GMPs for short. FDA is developing a roadmap for food and medical product manufacturers that will allow for better quality products, more effective risk management, and improved public health for all Americans.

Pharmaceutical GMPs

Our regulations for drug manufacturing haven’t been substantially updated in 25 years. Meanwhile, best practices in manufacturing have undergone significant progress, particularly in other high-tech industries which have adopted “six sigma” and other quality improvement methodologies.

And so, what we’re doing is overhauling and upgrading a body of outdated standards and requirements called the pharmaceutical Good Manufacturing Practices. We want to make sure that our regulations encourage progress, savings and quality improvements in medicine. Our new regulatory approaches are being

designed to encourage companies to continuously seek out and apply cost-reducing and precision-enhancing innovation in manufacturing and technology.

This project is still underway, and we are already seeing major progress in industry. We anticipate the pharmaceutical GMP initiatives will be completed by the end of this summer.

Food GMPs

Good Manufacturing Practices for foods are just as critical. FDA is currently undertaking two important initiatives — the modernization of the current food GMPs and development of GMPs for dietary supplement manufacturers — which are aimed at improving the quality of the foods that we eat and reducing the risk of adverse health effects to consumers.

The food GMPs were originally promulgated in the late 1970's and were last revised in 1986 in response to the identification of several newly emerging foodborne pathogens such as *Salmonella enteritidis*, and hemorrhagic *E. coli*. Food GMPs are an important part of the nation's control over food safety problems. Processing failures from a lack of the application of modern GMP controls are a major cause of food product recalls.

Since the last revision of food GMPs, we have continued to greatly expand our understanding of foodborne illness and have recognized the importance of several new bacterial, viral, and protozoan foodborne pathogens, such as *Listeria monocytogenes*, Norovirus, and *Cryptosporidium*. In many cases, these pathogens can be adequately controlled only by the implementation of appropriate GMPs by food-processing establishments.

Food allergens and certain other food ingredients are now recognized as a hazard for sensitive individuals. Cross-contamination of food products with a food allergen may also be prevented through the implementation of appropriate GMPs in food processing.

Rapid advances in food processing technology have also occurred since the GMPs were last revised. Modernization of the GMPs will be essential in creating opportunities for incorporation of newer technologies and better manufacturing techniques and process controls.

We believe this effort, like our work on current good manufacturing practices for medical products, will improve the safety of conventional foods and dietary supplements.

FDA (CFSAN) began the effort to examine the underlying health basis and enforceability of its preventive controls, including GMPs, by establishing a Food GMP Modernization Working Group in July of 2002. This working group

12 Association of Food and Drug Officials

initiated research in two areas: the impact of current GMPs on food safety, and the impact of revised GMPs on food safety and the likely economic impact of such revisions.

To date, the GMP Modernization Working Group has completed a literature review related to GMPs and a solicitation of expert opinions, which will contribute to a qualitative evaluation of food risks and the ability of different preventive measures to address those risks.

I am pleased to announce that, as a part of this continuing process to modernize the food GMPs, FDA will hold three public meetings this summer to obtain stakeholder input (especially from small businesses) on ways in which the food GMPs should be updated. These meetings will be held in different regions of the country, with one in College Park, MD, one in Chicago, IL, and one in Monterey, CA. The three meetings were just announced in the Federal Register and include a list of specific questions about food GMP modernization that FDA would like participants to address.

FDA intends to evaluate the data and information received from these public meetings to determine appropriate revisions to food GMP regulations. We will be accepting written comments through September 10, 2004, at which point we will proceed with rulemaking.

In concert with this review and modernization of food GMPs, FDA is also pushing hard on finalizing the first GMP guidelines for dietary supplement manufacturers.

Consumer interest in dietary supplements has increased exponentially in recent years. According to a recent Institute of Medicine report, American consumers are spending \$18 billion annually on dietary supplements, and there are about 29,000 such products on the market, with another 1,000 new products introduced each year.

Last spring, FDA proposed comprehensive new regulations that will set manufacturing and labeling standards for the first time for all dietary supplements marketed in the United States, focusing on their quality, consistency and potency.

When finalized, this rule will help protect consumers from dietary supplements that contain impurities or contaminants as a result of how they are manufactured or handled. It will also place dietary supplement labeling under closer scrutiny. Dietary supplement labels cannot claim the supplement will treat or cure a disease, and since December 2002 FDA has worked with the Federal Trade Commission to challenge false claims of supplement effectiveness for treating a range of diseases.

In short, the dietary supplement GMPs will eliminate the “buyer beware” situation Americans now commonly face when they purchase these types of health products.

In keeping with our risk management strategy, FDA will continue to coordinate future revisions of the food GMPs with dietary supplement GMPs to ensure we are doing all we can to protect and advance the public health.

Dietary Supplement Enforcement Strategy

FDA is also outlining a science-based approach to enforcement in order to protect American consumers from unsafe and/or misleading dietary supplements.

FDA has focused its enforcement efforts over the past year to ensure consumers are not being harmed as a result of claims that overstate the effectiveness of dietary supplement products. In the last 6 months alone, FDA has:

- inspected 180 domestic dietary supplement manufacturers
- sent 119 warning letters to dietary supplement distributors
- refused entry to 1,171 foreign shipments of dietary supplements and
- seized or supervised the voluntary destruction of almost \$18 million worth of mislabeled or adulterated products.

Most notably, dietary supplements containing ephedrine alkaloids have been taken off the market. These products were extensively promoted for aiding weight control and boosting sports performance and energy. The totality of the available data showed little evidence of ephedra’s effectiveness except for modest, short-term weight loss without any clear health benefit, while confirming that the substance raises blood pressure and otherwise stresses the circulatory system. These effects are linked to significant adverse health outcomes, including heart attack and stroke.

In March FDA requested that 23 companies cease distributing dietary supplements containing androstenedione, which are marketed to stimulate testosterone and muscle growth but have anabolic steroid effects in the body. This set of products poses substantial safety risks to all Americans, particularly our nation’s youth and athletes.

One of the key messages of this effort is that there are no safe quick fixes when it comes to losing weight and improving athletic performance, and it is only through proper diets, nutrition and exercise that we can improve our performance and, more importantly, improve our health.

14 Association of Food and Drug Officials

Over the next several months, we will be building out our enforcement strategy and utilizing every tool available under DSHEA to act against unsafe supplements and false or misleading supplement labeling claims.

This includes developing approaches to systematically review the evidence about the safety of individual dietary supplements. FDA expects to evaluate the available pharmacology, published literature (including animal, in vitro, epidemiological and clinical trial data) evidence-based reviews, and adverse event information — the approach that formed the scientific foundation for FDA's recent rulemaking on ephedra.

CONCLUSION

I thank you for your attention, and for the opportunity to share with you some of FDA's current priorities for protecting and advancing the public health. Thank you.

CANADIAN KEYNOTE

“Setting the Bar for Health Products and Food Safety: Serving Canadians Now and into the Future”

Diane Gorman
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

Introduction

Thank you, Guy, for that kind introduction. And good morning, ladies and gentlemen.

It is, in fact, entirely my pleasure to be here again this morning, to speak at this very important gathering of friends and colleagues from across North America.

This is the fourth time I have been invited to an AFDO conference, to update you about what we in Canada, and particularly in the Health Products and Food Branch of Health Canada, are doing in the area of food and drug regulation. Every year, the exercise of pulling together my remarks gives me a rare and welcome opportunity to reflect on where we have been and where we're going.

And if I may say so, the story I'm privileged to bring you becomes increasingly more positive with each passing year.

I won't pretend for a moment that we have addressed every challenge in that vast regulatory realm in which we all toil. Given the nature and complexity of our work, I don't think there is anyone among us, including my international counterparts, who would want to make that claim. No doubt we would be proven wrong in a matter of weeks, if not days!

But I *will* say that we are making some remarkable progress in Canada. Over the past year, we have introduced a number of interesting innovations in the way we function and the way we serve the needs of Canadians.

And there's much more to come: We are now putting the final touches on a strategic plan that will guide us — and guide us well, we trust — until 2007.

In the time available to me this morning, I intend to outline some of these developments for you, in the context of the emerging issues and challenges we share on this continent.

Context

The organization of today's agenda is no accident. We'll be hearing in sequence from representatives of the FDA, myself, the USDA, our Mexican counterparts, and the CDC. Three countries, each with its own domestic issues, to be sure. But also a lot of issues, opportunities and challenges that are common across borders.

Think back, for instance, to May 20th, 2003. That's the day a single cow, slaughtered in Alberta, Canada, was discovered to have been sick with BSE. One cow.

And yet, despite ongoing negotiations at the highest political levels, our \$2.2-billion beef export industry continues, 13 months later, to feel the effects of international trade bans.

Even as our North American economic market strengthens and grows, our globe — paradoxically — is shrinking. Which is both a marvellous thing and a constant challenge to us all.

Exciting ideas and innovations move instantly around our wired world. Huge international collaborations are propelling the pace of scientific discovery to such dazzling heights that notions like genomics, proteomics and nanotechnology — so recently foreign to most of us — have become practically commonplace.

With the good, though, comes the not-so-good: Once-distant threats have moved in next door. Alarming new pathogens like the SARS virus are just a quick airplane ride from our shores. And biological and other forms of terrorism have forced us to retool our notions of public safety and security.

The new century brings with it other types of public health challenges. Yes, we're living longer and generally healthier lives. But that also means our population is aging, with all the associated burdens and ailments.

Lifestyle-related conditions too may vary from one country and one decade to the next, but there will always be fresh challenges. In Canada, for instance, our modern smoking rates are mercifully low by global standards, but our rates of obesity and diabetes are way up — especially among Aboriginal Canadians.

This is the complicated world we live in today — the world we all share. As regulators, we have little choice but to embrace the opportunities it presents to us while preparing ourselves for its challenges.

Overview of Canadian approach

Permit me to describe for you the approach we have been adopting in Canada. As I mentioned earlier, our Health Products and Food Branch is about to launch a three-year strategic plan.

It is an important step forward for us, because it captures in a coherent way the thinking, the principles and the practices that have been crystallizing across the Branch over the past few years as we grapple with our changing environment.

I am very proud of the document, because it tells our stakeholders that we have been doing (and will continue to do) some great things for the people of Canada.

It is a major milestone in the evolution of our organization and our commitment to world-class delivery of our mandate. In short, it is our tool for demonstrating progress against our commitment to serving Canadians.

In a nutshell, we're telling Canadians how we will ensure they have:

- timely access to safe and effective health products
- safe and nutritious food, and
- the information they need to make healthy choices.

How do we intend to accomplish this daunting menu of deliverables? By focusing on the essentials. Essentials like:

One: improving the efficiency, effectiveness and responsiveness of our regulatory processes.

Two: enhancing the transparency of our processes, so that we build stronger relationships with stakeholders, boost public trust, and demonstrate our accountability to Canadians.

Three: strengthening our capacity to respond to public health issues, including safety concerns that affect food and therapeutic products once they are already in the Canadian market.

And four, offering Canadians the kind of authoritative information they need to help them make healthy and informed choices in their lives.

This last is particularly important, I think, because it recognizes the expanding role of regulators in the health system.

Although it remains central to what we do, we are no longer only in the business of health protection. In the world of modern regulation in Canada, we also have a

key role to play in health promotion, in generating and providing to our citizens, at both the individual and population levels, the authoritative information they need to take ownership of their own health.

We have a role to play in understanding not only the risks but also the benefits of what we regulate, and making that known to our respective publics.

There is a fifth essential element to our strategic plan as well. It recognizes perhaps more explicitly than the others that the environment we work in is constantly changing, creating new challenges.

Thus, it is our goal to create an organization with business processes that make us flexible, responsive and internationally engaged — ready to embrace the opportunities and confront the challenges of tomorrow.

You'll be relieved to know, I'm sure, that I do not intend to walk you through a comprehensive laundry list of all our activities and initiatives over the past year or so. Our web site provides a wealth of such detail, and I invite you to visit at your leisure!

Instead, I propose to use the next few minutes to give you the big picture, to select a few choice examples to illustrate how we are moving toward each of our five strategic goals.

1. Better regulatory processes

Our principal purpose as a regulator is, of course, to monitor and evaluate foods and health products in such a way that Canadians can continue to have the utmost confidence in their safety and efficacy. Confidence that their food is safe and of high quality. That their medicines, medical devices, blood products, transplant organs and so on are safe and effective. Confidence, moreover, that they will have access to these products, as and when they need them.

Toward those ends, we have been modernizing our legislative tools, policy frameworks and regulatory approaches to ensure that our processes are efficient, effective and responsive. We are pursuing “a regulatory platform for the 21st century” that is flexible, risk-based, and geared toward promoting innovation while fully protecting health.

But what does that really mean? Let me give you two examples.

Some of you may know that Canada has developed a new regulatory framework for human cells, tissues and organs for transplantation, set to come into force over the next two years. This is, obviously, a complicated endeavour. On the one hand,

it is critically important that Canadians be protected with safe, high-quality transplant products. On the other, we do not wish to ensnare this fast-growing, leading-edge field of medicine with burdensome and unresponsive regulations.

We found the solution in standards-based regulations — regulations that reference standards drawn up by the leading minds in the transplantation field, aided by a highly regarded, independent standards-writing organization.

While similar models have been used with success in Canada in the food industry, our new CTO regulations mark the first time in Canada that national standards have been developed for something considered an area of medical practice.

It's an elegant solution that we believe will allow us to serve the interests of Canadians with modern and relevant regulations that will keep pace with a rapidly evolving sector of health care.

The second example relates to our Therapeutics Access Strategy, which we adopted last year. It's a broad, all-encompassing strategy that affects many aspects of our Branch. But, as the name suggests, its key goal is to improve the access of Canadians to innovative drugs and other health products — the products they need to maintain and improve their well-being.

From a regulatory perspective, that includes examining the basics of how we regulate – everything from re-engineering our business processes to improving our dispute resolution mechanisms. In particular, in the short term, we are working on measures that can move submissions through the review process more efficiently, while still maintaining our high standards of safety — a perennial challenge for product regulators the world over.

To do this, we are completely revamping our review process to align it with modern project management principles. We are communicating at an earlier stage with sponsors to ensure a higher quality of submission. We are ensuring that guidance documents, SOPs and templates used by industry stakeholders and our own review staff are clear and consistent.

Along with other efficiency measures like developing our capacity to accept, process and track electronic drug submissions, we're working toward a review system that is timely, consistent, predictable and of top quality.

Through these efforts, I'm pleased to note we have all but eliminated a serious backlog in pharmaceutical submissions, and we are very well placed to meet performance targets across all our product lines. And this, of course, is key in our efforts to contribute, along with industry and other partners, to improved consumer access to safe and effective therapies.

2. Transparency and accountability

I mentioned earlier the paramount importance of public trust — the confidence of Canadians in the safety of their foods and health products.

But trust doesn't spring up, fully formed, at the end of the process — when the food is on the table or the pill is being swallowed. As regulators, we must be aware that stakeholders in this modern day expect more. They want to be informed about, and engaged in, our processes. They want to know what we are doing, how we're doing it, and why.

This transparency is the foundation of a strong and healthy relationship with the people we serve — whether that's industry, health professionals or consumers. Transparency translates into understanding, and understanding leads to trust and confidence. It's the very essence of government accountability.

Enhancing the transparency of our operations is a major focus of our forward agenda at HPFB. In the last year, we have interacted with more than 100 consumer and public groups, and the numbers only promise to keep growing.

Let me illustrate what I mean by telling you about several projects we've undertaken to open up the doors of our organization to our stakeholders and the public.

Last year, on two occasions, we took the unprecedented step of holding a two-day deliberative session that brought over 50 of our key stakeholders, including representatives from consumer, patient and industry groups, together to discuss and ultimately present their views on regulatory system improvement to our Minister and Deputy Minister of Health.

The session was unique in its approach to multi-stakeholder engagement on these issues. The discussion was vigorous, as you can imagine. The insights we obtained, however, into how we are perceived as an organization and what we needed to do to meet stakeholder needs and expectations were invaluable. They have provided us with a sound basis for continued transparency and dialogue as fundamental elements in the way HPFB fulfills its mandate.

On a pilot basis, we are also moving forward in making information about the

products we regulate and how we make decisions about them more accessible to Canadians. We are now publishing on the Web the summary basis of regulatory decisions for two therapeutic products, with a view to gaining feedback from both industry and the public on how we can implement this project more widely. This marks the first time that this type of “Made in Canada” information has been accessible to both health professionals and the public. We’re also working with industry to add consumer-targeted information to all product monographs in the near future.

I’m also very excited about another project we are just getting off the ground in our Biologics and Genetic Technologies Directorate. We are collaborating with a complete outsider — an anthropologist from a Nova Scotia university — in a project that will describe to the public how medications are reviewed and approved by government regulators.

She’ll have unfettered and independent access to three complete submissions, from start to finish, and to the reviewers and industry sponsors as well. And she will report publicly on what she finds — everything except the names of the products.

We have made a commitment to become more transparent about our processes, and we need to be proactive in accomplishing that. Our hope is that this study will help shed some light on our work and lead to a better informed dialogue with the public and with industry.

We’re confident that Canadians can only gain through a more thorough understanding of our drug-review processes.

3. Vigilance and responsiveness

So, our first priority is about carrying out our jobs at peak performance, so that safe and effective therapeutic products, along with safe, high-quality foods, are approved for sale in Canada.

Our second priority is to let Canadians in on how we achieve this.

But that’s still just half the story. The scope of our regulatory responsibilities also extends to what happens once a regulated product is actually out there and used by consumers.

We all know that, no matter how thorough our review processes, we can never know with certainty what will happen once the product is being used in real-world situations.

That’s why our *third* priority focuses on a variety of exciting initiatives to improve the safety of marketed health products and strengthening our compliance and enforcement activities.

For example, in collaboration with a coalition of health care organizations we are developing a world-leading system to improve patient safety by reducing the chances that patients are harmed by the very medicines they take to make them better – the Canada-wide Medication Incident Reporting and Prevention System.

The system, known as CMIRPS, is much more than a database. It actually brings together experts to look at all the surrounding circumstances – product labelling, institutional practices, human behaviours – that can contribute to the improper administration of medications. It is, in my view, our flagship contribution to patient safety in Canada.

And we’re taking another big step beyond such “passive” ADR reporting. In collaboration with the Canadian Paediatric Society and other partners, we are undertaking a first-ever active surveillance project to detect and track adverse drug reactions among children. Under the program, more than 2,300 paediatricians and other child-health specialists will be reporting to us on serious or life-threatening adverse drug reactions in children. It is our hope that this project will help us to address what we all know is a widespread shortage of medical data, in Canada and around the world, about the youngest members of our populations.

4. Authoritative information

Our fourth strategic direction captures the idea that, when it comes to enhancing the safety and well-being of Canadians, regulatory authorities have a key role to play in helping citizens manage their own health.

In an age where consumers can be overwhelmed by information — some of dubious provenance — one of our key priorities is to ensure they can turn to us for the definitive, authoritative word on the products we regulate.

Over the past year, for instance, we’ve brought in clear and user-friendly new nutrition labelling regulations.

We’re also updating *Canada’s Food Guide to Healthy Eating* – a publication produced for decades by Health Canada that, I’m told, is in the top ten most requested government publications and is virtually required reading in every school district across the country. Our goal this time around is to ensure the guide continues to reflect the most up-to-date nutrition information available and that it delivers this information in a way that is easily understood and practically useful to the public.

And we're partnering with Statistics Canada, our country's central statistical agency, on a comprehensive survey of the eating habits of Canadians – the first such survey in a generation. We can talk all we want about obesity, diabetes and nutrition, but our discussions will be much better informed once we pull together data on what 30,000 Canadians actually put in their mouths.

Our focus on enhanced consumer information extends beyond food, of course. As I mentioned earlier, we will soon demand better product monographs for all drug products, containing information geared specifically to consumers.

And new regulations for natural health products, which took effect this year, will oblige these 50,000-plus products to be labelled with complete and accurate information on content, cautions and use.

5. Modern organization

Doing our jobs well for today is crucial, of course. But at the same time, we must not lose sight of our responsibilities for tomorrow.

That is why our fifth and final priority focuses on the future and on the rapidly changing environment I spoke about earlier, the kinds of new opportunities, challenges and pressures that will confront us all.

That sort of operational readiness demands a forward-thinking transformation. We have to retool a range of structures and procedures to ensure we will have the kind of flexible and responsive organization we need.

And so, we're addressing a broad range of issues, like human-resource planning, management practices, the strategic use of information technology, and so on.

We're also enhancing our regulatory cooperation and information-sharing with international counterparts with informal collaborations and exchanges and formal instruments like MOUs, the Global Harmonization Task Force and the Trilateral Charter that we signed with the U.S. and Mexico last January.

I'd like to particularly mention that, in the last year, we have concluded MOUs with both the FDA and Australia's Therapeutic Goods Agency, which promise to bring many opportunities to our respective organizations for information sharing and cooperation on issues of mutual interest.

Our goal is not just to better fulfill our existing mandate in the domestic public interest, but also to be able to anticipate and respond effectively to emerging bio-terrorist threats or other health-related emergencies of global concern.

Conclusion

Each of us here today is in the business of food and drug regulation. Our day-to-day jobs often find us immersed in the details, the minutiae of product review and post-market vigilance.

Every so often, however, it helps to step back. To look at the big picture. To evaluate what we do, and how we do it, against a broader context. Our own domestic context, for starters, but also a context that is undeniably more global and intertwined with each passing day.

Canada has always been an outward-looking nation; our history is characterized by the deep connections Canadians feel to our roots around the world and the important value we place on our role and our relationships in the global community.

That same perspective applies to the Health Products and Food Branch. Our focus is on advancing the best interests of Canadians, but the approach we bring to the task is international in scope.

Those of us who share space on the North American continent know that we also share trade, prosperity and economic opportunity. There is much that binds us.

Our common interests mean we can work better together. We can learn from each other and harmonize our practices in a way that gives our respective citizens speedier access to the products they need.

But we can't just look to today. We must always be thinking about tomorrow. We must equip ourselves to deal with a changing world — a world that is changing quickly and presents both challenges and opportunities.

This conference gives us a most valuable opportunity to look beyond our day-to-day duties, to see beyond our borders. And to fashion the kind of perspectives and partnerships we need to confront the future, together.

So thank you for this opportunity, and thank you for listening.

GLENN W. KILPATRICK MEMORIAL ADDRESS

Colin Broughton, Ph.D.
Health Products and Food Branch
Health Canada

Good afternoon everyone.

I am very pleased to present the Glenn W. Kilpatrick Memorial Address at this, the 108th annual meeting of the Association of Food and Drug Officials

Glenn was very much a futurist and I have therefore chosen to highlight, in lay terms, since we have guests with us, some of the leading edge scientific work currently underway that will soon result in novel products that will present us with new regulatory challenges. I will also suggest how AFDO can capitalize on this fascinating new world which is opening daily before us.

Glenn Kilpatrick was a staunch supporter of AFDO, seeing it as we do, a forum where knowledge is shared and where we can all participate for the greater good. Not only here, at the Annual Educational Conference, but throughout the year as we contribute our knowledge to the work of our Committees studying issues of interest to us. To continue to give freely of our time as volunteers we must see results that are relevant to us. Over the years, we have seen, through iterative processes using snail mail, fax or email, the creation of some real state-of-the-art works by AFDO members which have been used by both industry and regulators, since they were created by the best minds in the business and described current expectations as we continue to move forward in ensuring that the food, drugs and medical devices sold throughout North America are safe to consume or use. Perhaps the best example of this that I can point to is the result of many months of work by members to create AFDO's Food Code and which is now available to all who need this information bringing together, as it does, the input of those knowledgeable members who gave freely of their time for the benefit of all. There are many other examples where AFDO members have addressed current regulatory issues and published what we consider to be a best-practice and which now reside in the archives of AFDO where they are available for mining as and when we need them.

A number of our Codes are on display near our Reception for your review and I urge you to take a look at the breadth of subjects that have been reported on by AFDO members. They cover such issues as Managing Food Emergencies, Can Defect Assessments, and Fish Curing.

A few weeks ago, in speaking with one of my communication's colleagues, he asked "How old is AFDO"? When I said 108 years, he said "WOW, to have been around 108 years it must still have relevance". **And it has.**

Some 20 years ago, when I attended my first AFDO meeting, our world revolved around food and drug safety and I well remember that we at Health Canada went into discussions at that time with a multinational pharmaceutical company seeking approval for their new insulin manufactured not from animals. This was my first introduction to biotechnology, and this branch of science now impacts all the product classes we regulate. My regulatory world today encompasses the safety of food, drugs (both for human and animal use), dietary supplements, vaccines, blood, blood products, human tissues and organs for transplanting, as well as the safety of animal tissues to be transplanted in humans. We also ensure that semen is safe through semen bank inspection.

This list continues to grow but more importantly, the way these products are made continues to evolve.

For all of us, our regulatory world has changed mainly due to the coming of age of biotechnology and its integration with chemistry, the digital world and now nanotechnology. Furthermore, this convergence will continue to grow at a steep rate increasingly challenging us with novel products.

Ethical concerns have been expressed over the use of animals that have been genetically altered to produce a chemical that is foreign to that species but seen as useful to humans, as for example, a drug. Then along came the lowly tobacco plant which, because of its rapid growth and other genetic attributes but also because the researchers did not want to use a plant with commercial food value as the host for their experiments, many researchers are now working with genetically altered tobacco plants to produce bio-chemicals for our use.

Let me speak about a number of exciting developments and related challenges from this world of merging technologies and emerging applications, leading to products which we will shortly be regulating as they seek to enter the marketplace.

The convergence of existing with emerging technologies will always present us with regulatory challenges and will force further adoption of a risk-based rather than a product-based approach to organizing and executing regulatory oversight. Most of us are familiar with the research work to enhance in fruits and vegetables the levels of micronutrients and chemicals considered to be of benefit. An example is enhanced lycopene levels in tomatoes. Well, this is only the beginning.

Work is well under way developing medical devices that combine leading-edge technologies such as biotechnology, nanotechnology and electronics. Imagine an implanted device that measures the concentration of a selected problem biochemical in our bloodstream and reacts to the finding by doing nothing if all is OK or by delivering an agent to decrease the level of the problem biochemical, or that transmits the information to an implanted electromechanical unit that reacts appropriately.

Nanotechnology is expected to strain the regulatory system. Nanoparticles can be used as a drug delivery vehicle by encapsulating a drug, which they will transport with pinpoint accuracy to the place where it is needed in the body. Magnetic nanoparticles are being investigated to be used directly as anti-cancer agents. After selective attachment to their target tumour cells, an alternating magnetic field is applied which causes them to heat up and thereby kill the tumour cells.

Some observers believe the regulatory challenges from nanotechnology, including those of a social and ethical nature, will dwarf those we have seen from biotechnology. How we go about developing the scientific oversight and the public debate on the pluses and minuses of nanotechnologies will speak volumes about whether we have learned lessons from our experience with biotechnology.

Molecular farming is the term now being used to describe the production by genetically modified plants or animals of useful products. As I mentioned a few moments ago, the lowly Tobacco plant has a new use in life in this regard. Many companies have invested heavily in this research and development, to the point where very many small-scale trials, are currently underway here in the US and elsewhere.

We have, for example, tobacco plants that have been engineered to produce interleukin 10, a drug to treat Crohn's disease, a painful bowel disorder, and interleukin 4 for the treatment of autoimmune juvenile diabetes. The regulatory challenge here is to ensure consistent pharmaceutical-quality active agents from plants that are growing and subject to, fluctuating environmental conditions, producing large complex compounds that cannot always be characterized easily and that have to be separated from the thousands of other proteins in the harvested material since unwanted plant residues may cause allergic-type reactions in patients. At least with the tobacco plant, we do not have the potential problem of contamination of the food supply by food crops containing pharmaceuticals through accidental mixing or pollen drift. While the protests go on, we still have animals being used to produce chemicals of use to humans. An example are goats that have been genetically modified and now produce an antidote to nerve agents.

The regulatory challenges here are to keep these animals out of the food system and determining the proper means of disposing of animal waste and by-products to prevent harming environmental and human health. Compliance has already been a problem in this fledgling molecular farming industry, from the accidental release of genetically modified animal carcasses to rendering plants to the flagrant disregard of an inspector's instructions, which resulted in the mandatory destruction of a considerable amount of soybeans.

Solid conversation between regulators, the incipient industries, and other stakeholders should take place to provide a regulatory environment, which will allow the benefits of molecular farming to accrue, based on a sufficient understanding and the management of any safety risks.

We are all on the learning curve – the innovators, the manufacturers and regulators alike. We all need to strive for a harmonized international approach to regulation of this exciting field of molecular farming. We will expect biologics derived from plants or animals to be as rigorously produced and meet the same high quality and safety standards as other biopharmaceuticals made in microbial or mammalian cells.

As we move our scan further out we come across research being carried out capitalizing on our ability to map each of us genetically. Then, through monoclonal antibody technologies, the expectation is to design medication which will be specific to each of us separately for our condition, thereby markedly reducing the side-effects or long-term problems some people today experience with their prescribed medication.

One thing is for sure, the regulatory community will need to be flexible as never before. It is as unacceptable to block the introduction of a safe but innovative and genuinely useful new product because of an inefficient and maladaptive oversight system, as it is to allow the introduction of an unsafe one because of an ineffective oversight system. The regulators of our near future will need to be on the ball and I am pleased to tell you that we in North America, along with colleagues in Europe, have a number of draft guidelines under development designed to ensure the continued safety of humans, animals and plants. We can expect to be involved in not only regulating the products but also the process, from planting to harvest through processing. Issues such as the regulatory status of a field, a greenhouse or a mine will need to be carefully thought through along with the health impacts on workers or bystanders and wild animals.

As these products are being developed, we, the regulators need to be with them. Reaching out and seeing new members join AFDO from these areas will help all of us better understand these rapidly developing areas which will soon impact all of us, whether as regulators or consumers. And more selfishly, we will see our ranks swell as we stay relevant for another 108 years. Let us reach out to them by offering AFDO as the umbrella under which they can dialogue with their colleagues in their own parallel workshops as part of our program. My information is they do not have a venue that is product regulatory based as AFDO is. Are their ranks expected to swell? You bet.

In closing let me say that I hope in some small way I have indicated one of several areas we must embrace if AFDO is to continue to have relevance to both the regulators and the industry whose novel products our publics will expect us to regulate.

Thank you for the opportunity to deliver the Glenn W. Kilpatrick Memorial Address at this, the 108th Annual Convention of AFDO, and thank you for your attention.

PRESIDENTIAL ADDRESS

Delivered by Christopher Wogee
President, Association of Food and Drug Officials

During my life, I have heard many great speeches. I don't believe this speech will be regarded as great, but I think that its messages are important and should be of value to all food, drug, medical device and consumer product regulators, manufacturers and marketers. This speech is the high point of my year as AFDO's President. It has been a difficult year, with many challenges, but it has very been interesting, full and informative.

But before I get into the body of my speech, I'd like to thank all of you for attending the 108th Annual Educational Conference of the Association of Food and Drug Officials. In the next three days, you will be addressed by some of the most important speakers in the field of consumer product health and safety and updated on the major issues of today. You will also have the opportunity to meet and confer with your peers, your competitors and key persons that impact the consumer health of our nation and the world. To assemble such a group of experts takes the donated time and energy of many people. I'd like to publicly thank all of those who planned and will conduct this conference. These include representatives from the Great State of Pennsylvania and the historic city of Pittsburgh, the Board and members of the Central Atlantic States Association, the Local Arrangements Committee led by Steve Steingart, our Federal partners, FDA, USDA, CDC and DHS, AFDO's Associate Members, the AFDO Affiliates, the AFDO Board of Directors and all those who will present to us in the next few days. I will not overlook the contribution of the AFDO office staff including Executive Director Denise Rooney and her staff Shirley Bortner and Cathy Misfud. They are in Pittsburgh to help you make full use of what's here and find full value in your conference attendance and AFDO membership. I certainly must extend a special welcome to those who are first time attendees and I would also be remiss if I left out a key person in making this year's conference happen. My thanks to the Conference Chair, AFDO Vice-President Dr. Marion Aller. I thank all of you for bringing this event together. Your hard work will be paid back with much more hard work in the future and hopefully a great amount of satisfaction.

It is June 20, 2004, and we sit together in a great room facing two hours of ceremony before we can relax or initiate our personal and career agendas of networking and collaboration. We are all anxious, stressed and tired. We look at the next three days as an opportunity but in the back of our minds we know that we have stepped away from the huge workloads that don't care if we are at the AFDO Annual Education Conference or if we are ill, away at a family emergency or stranded at some airport. To make up for these four or five days in Pittsburgh, you will all have to cram eight days of work into your next five calendar days. Your being here shows a deep-rooted dedication to food, drug, medical device and cosmetic safety.

This has been a very busy year for AFDO and in some ways, a disappointing year. AFDO has not attained all of its strategic plan goals. It is very difficult for an organization such as AFDO to feel comfortable when our nation is threatened by terrorists and at war. It is a major interest of AFDO to ensure that food, drugs, and other consumer products are protected from tampering, counterfeiting and any conceivable terrorist threat. To a threat, it is vital that local, state and federal regulatory agencies work closely together without barriers that block rapid communication, information sharing and close and mutually beneficial working relationships. AFDO will continue to work for a national food antiterrorism system that integrates all levels of food and drug regulators, law enforcement and industry.

In this goal, I feel that we are far from being ready to detect or prevent a threat to public safety and our national economy. Our ability to quickly and effectively work together to respond, limit and recover from an attack is not assured. AFDO invites all agencies, all industries and all organizations to strive to work together. When it comes to preparing to protect our nation's consumers, turf battles, bureaucratic delays and ineffective unilateral actions only delay the day when our readiness will absolutely discourage any attack upon our food supply. AFDO will continue to press for an integrated national food safety strategy and pledges to work with all groups of like mind and like determination. AFDO's biosecurity efforts are led by its three Work Group Chairs, Doug Saunders of Virginia, John Tilden of Michigan and Paul Tierney of Massachusetts. They have worked very hard in this endeavor and I thank them now. I also will warn them that their job is not done and hope they can carry out our intended mission to forge a national food biosecurity strategy from the various pieces that exist now. It is so very important for the nation's future that it has to be the top priority for AFDO.

Many years ago, there was a newspaper comic strip character named "Pogo" who lived in the swamps of Georgia. He was quoted to say "We have met the enemy and he is us!" AFDO has spent much time in a battle of words and ideas that has lasted almost a decade over something that should have been satisfactorily resolved by common sense, logic and mutual need. This battle is over legislation that is called by its backers "National Uniformity." Now the nation's legislators ponder a bill that threatens our food and drug structure by preempting most state laws that provide authority for state food inspection and regulation programs. The original concept of the bill was to prevent states from having laws regarding labeling, warnings, and standards that are different from those of the federal government. Support for the bill was borne from such state laws that set local standards and requirements like California's Proposition 65. The current bill, HR 2699, goes far beyond this original concept and negates all state and local food laws that are not "identical" or adopted in an "identical" manner to federal law. This virtually eliminates all state food laws, even in those states where federal regulations have been adopted verbatim. My fear is that if this bill passed as written, and there is a strong effort to pass it without modification or public debate, this country will lose more than 80% of its food regulation capacity. It is

unlikely that FDA, USDA or any other federal organization can replace the work done by the states nor is there a surplus in the U.S. budget to spend between \$500 million and \$1 billion to pick up the work that will be lost. I ask you, is this the time to eliminate a major portion of food protection? Foodborne illness outbreaks continue to occur, unsafe and misbranded products are detected every day, and the threat of terrorist acts is not diminishing.

AFDO will continue to inform all who will listen to the truth about HR 2699. Many states have already recognized the threat and I thank them for their legal opinions. AFDO will continue to fight the passage of this bill. It is bad law and tantamount to uncontrolled and irresponsible deregulation. Our champion in this effort to prevent passage of a bad law is a person I admire greatly. She is a retired state employee from Florida and works tirelessly to bring out the truth about the "National Uniformity Bill." She is Betsy Woodward and continues to be AFDO's articulate voice and conscience on this issue. She does not hesitate to take on any threat to America's food safety, no matter who or why. I thank her for her efforts and support her with all my heart. Betsy and AFDO will continue to look at this and all legislation to ensure that it serves public health.

In the past year, AFDO has vigorously promoted the programs and initiatives of our federal partners. AFDO fully supports such national initiatives as national adoption of the Food Code, dealing effectively through education and training with the food safety threats posed by emerging pathogens, limiting the use of tobacco products, properly addressing the health risks posed by obesity, increasing food safety by using innovative programs such as Hazard Analysis and Critical Control Point food safety systems, removing from sale unsafe, misbranded and/or falsely advertised dietary supplements, and educating industry and regulators about food, drug, medical device and cosmetic safety through standardized training programs such as given by FDA's ORA-U or through organizations including AFDO such as retail meat safety, seafood HACCP, conducting effective food recalls and dealing with food safety emergencies.

AFDO has just embarked on a new national effort initiated by USDA to look at how a national food consumer complaint program can be established. Imagine, all food complaints being received, analyzed and responded to such that foodborne illness outbreaks are quickly identified even if the illnesses are spread out and sporadic. FDA has joined in this national workgroup since such a system must address all food types, not just meat and poultry products. The potential of this system for recognizing problems and gathering data is great. The barriers to implementing such a system are also great. AFDO is not afraid to take it on and will do our best to do our share to develop a system that serves both the public's and the food industry's best interests.

In a like venture, AFDO has had preliminary discussions with CDC to find out why all foodborne illnesses do not get reported to CDC even though they may have been received on the local or state level. AFDO's recent survey of the accomplishments of state programs has shown that there is a vast disparity

between local, state and CDC data. Are we losing valuable data or are methods of data collection and illness accounting just flawed by diversity. CDC, AFDO is very interested in helping you find the answers.

This year's turnout for the Annual Conference is much lower than expected. I am discouraged by the inability of many AFDO members to attend this year due to shrinking budgets and increasing workloads. Most AFDO members can't attend and have to work their magic remotely in their respective committees and through AFDO's six great affiliates. I recognize state budgets are tight. The fat has been cut out of agency budgets and I'm afraid we are starting to lose some muscle and bone. Federal agencies are also seeing a draining away of staff, training opportunities and meeting times. AFDO is adjusting and has made efforts this year to bring more to you through eNEWS and on its web site. AFDO now has the computer hardware to expand online services to you. We are getting connected with a T-1 line, programmed and soon there will be a new world opening up for our members. Members, affiliates, and associates will all have greater communication resources. AFDO committees will have bulletin boards, online meetings and even chat rooms to do their important work. Laboratories will have more resources to communicate and share methods and data. Workgroups will have secure communications to share their information, especially any that must deal with threats against our national food supply. The changes are coming and it will bring AFDO into your office and be accessible when you need information or when it is convenient for you to interact with AFDO and your fellow members. In this effort, AFDO has been assisted by USDA grants and the leadership and hard work of Bill Kreuger from Minnesota. Thank you, USDA, and thank you, Lab Guy!

The President of AFDO has many duties, but the one that takes the most time and disrupts his or her life the most is doing speaking engagements. I have traveled many miles, visited many states and gone to a few places I never intended to go to. I even got to go to Reno, Albany, Pigeon Forge, New Orleans, Des Moines, San Juan, Rockville, Washington D.C., Lincoln and even Pittsburgh. In each place I found great potential and good people. I saw that AFDO's Affiliates are doing great work. AFDO's Affiliates are very important. I encourage all AFDO members to join their local affiliate and maybe a few others. The dues are trivial and the benefits are great.

In my travels, I have appreciated an effort by the AFDO Endowment Fund to look out for AFDO's future. Efforts by Dan Smyly, John Young, Bill Spain and others to gain funding for the AFDO Endowment Funding have been successful, but not so successful that each one of you should not take a little time during the conference to find out more about the AFDO Endowment Fund and make a donation to the future of AFDO. AFDO is more than 108 years old. The AFDO Endowment Fund's goal is to provide resources to fund training, work projects and AFDO expertise to ensure that AFDO is helping you and America another 108 years. Dan, John, Bill and all who donated, thank you.

I could talk for hours about what AFDO has done and will do but I think that will be better spoken by our actions here and in the coming year. Upon that note, I will close my presentation. I wish all of you a satisfying and productive meeting. It is AFDO's members that make AFDO a great organization. It has been a pleasure and an honor to serve as your president this year. AFDO is a great organization and a family that does so many good things. Thank you very much.

PRESIDENTIAL PROCEEDINGS

To obtain copies of the following documents, please contact the AFDO office.

National Uniformity Bill

Letter to Susan Stout, Grocery Manufacturers of America

Re: HR 2699

January 8, 2004

Letter to Congressman Richard Burr, North Carolina District 5

Re: HR 2699

January 12, 2004

Letter to Susan Stout, Grocery Manufacturers of America

January 20, 2004

Attachment: Concerns and Issues of the Association of Food and Drug Officials Relating to Uniformity Legislation (S 1155) Previously Filed in 106th Congress

Other Presidential Correspondence

Resolution Actions

Letter to Julie Gerberding, CDC

Re: Resolution Number 6 Food Testing to Detect Contamination from Terrorist Acts

July 28, 2003

Attachment: Resolution Number 6

Letter to Secretary Tom Ridge, U.S. Department of Homeland Security

Re: Resolution Number 5 Regulated Facilities and Commodities Considered High Risk for Bioterrorism

July 28, 2003

Attachment: Resolution Number 5

Letter to Elsa Murano, USDA/FSIS

Re: Resolution Number 6 Food Testing to Detect Contamination from Terrorist Acts

July 28, 2003

Attachment: Resolution Number 6

Letter to Lester Crawford, FDA

Re: Resolution Numbers 1, 3, 5 and 6

July 30, 2003

Attachments: Resolution Numbers 1, 2, 5 and 7

Miscellaneous

Letter to James Baker, FTC

Re: FTC's Preliminary Strategic Plan for Fiscal Years 2003 through 2008
July 11, 2003

Letter to Secretaries, Commissioners or Directors of Agriculture and Health

Re: ODP/DHS State Homeland Security Grants Program Assessment
September 4, 2003

Letter to Secretaries, Commissioners or Directors of Agriculture and Health

Re: ODP/DHS State Homeland Security Grants Program Assessment
October 9, 2003

Letter to State Food Program Managers

Re: AFDO Vision of a National Food Security Project
December 17, 2003

Attachments: AFDO Vision of a National Food Security Project
Food Security Survey

Letter to Richard Barnes, FDA

Re: AFDO White Paper, "FDA Food Inspection Contracts: A Time for Change"
November 24, 2004

Attachment: AFDO White Paper

PRESENTATION OF ASSOCIATION AWARDS

The 2004 winner of the prestigious Wiley Award was **R. Douglas Saunders** of the VA Department of Agriculture. The Harvey Wiley Award is presented annually to an AFDO member who has demonstrated, through the performance of duties, outstanding service and devotion to the administration of food, drug, and consumer protection laws of our country.

The award is named in honor of Dr. Harvey Washington Wiley, Chief of the Bureau of Chemistry of the USDA in the early 1900s. Dr. Wiley's contribution to science and consumer protection coupled with his progressive advocacy for change and reform of food and drug regulations culminated in the passage of the Pure Food and Drug Act of 1906.

Dan S. Smyly, Ph.D., received the AFDO Sustained Superior Achievement Award in recognition of his many years of devoted service to AFDO. His unflinching efforts to fulfill AFDO's mission and vision, his devoted service, quality leadership and ability to bring AFDO members to consensus have been invaluable to AFDO and its affiliates.

The Associate member Award was presented to **John C. Young**, attorney with the law firm Young and Associates, which provides regulatory counseling and consulting in matters involving foods, drugs, and dietary supplements.

This award was presented to Mr. Young for his long-term active membership, active involvement in committee work, and his outstanding contribution and service to AFDO.

This year's Achievement Award was presented to **Tarsha Oliver** with the Illinois Dept. of Public Health, Division of Food, Drugs and Dairies. The award was presented for her sustained level of performance. As a postscript, Tarsha is also the mother of a daughter and quadruplet boys.

The George M Burditt and the Betsy B Woodward Scholarship Awards (both for \$1,500.00) were presented this year to two deserving candidates. The first award went to **Min Li Wu** who is attending Washington College in Chestertown, MD with an expected Bachelor of Science degree in Biology with a Chemistry minor. She presently has a GPA of 3.84.

Our second award went to **Karen Campbell** who is attending Oregon State University with an expected Bachelor of Science degree in Food Science and Technology. She presently has a GPA of 3.88.

Committee Award Recipients:

- **Denis Blank** received a Committee Award in recognition of his contributions to improve AFDO membership and his guidance as chair of the membership committee.
- **Marion Aller** received a Committee Award in recognition of her outstanding dedication and commitment as annual conference program chair and her leadership in national uniformity.
- **Steve Steingart** received a Committee Award in recognition of his service as chairman of the 2004 Local Arrangements Committee and as co-chair of the media and public affairs committee.

Special Recognition Award Recipients:

- **Bill Krueger**, in grateful recognition for his outstanding dedication and commitment toward resolving national laboratory related issues.
- **Gerald Wojtla**, in grateful recognition for his outstanding service and leadership in resolving issues and providing guidance in relation to inspector and investigator field issues.
- **John Tilden**, in grateful recognition for his outstanding leadership and innovation in promoting food security and counterterrorism as co-chair of AFDO's multi-state food security taskforce.
- **Paul Tierney**, in grateful recognition for his outstanding leadership and innovation in promoting food security and counter terrorism as co-chair of AFDO's multi-state food security task force.

Betsy Woodward received a Trusted Advisor award for her outstanding leadership in support of state and local health programs.

Thomas W. Brooks received an award for his outstanding service as Editor of the *AFDO Journal*.

An award was presented to **Kenneth W. Hohe** for his outstanding service as Editor of AFDO "News and Views".

Alfred Bugenhagen received an award in recognition of his dedication and guidance as AFDO's Secretary/Treasurer.

Congratulations to all the winners for their well-deserved awards.

CONSTITUTION AND BYLAW AMENDMENTS

In accordance with Article XIV of the Constitution and Article X and XX of the By-Laws, the following change was approved by AFDO voting members.

1. Addition of a Department of Homeland Security (DHS) Advisor to the AFDO Board of Directors. This individual is a non-voting board member.

This change better reflects AFDO's current critical business relationships with federal agencies that have food safety and food security responsibilities.

CONSTITUTION:

ARTICLE V - BOARD OF DIRECTORS

Section 1: The affairs and business of the Association shall be conducted by a Board of Directors composed of two (2) elected directors who are elected at large, one (1) elected director from each Regional Association Affiliate, the immediate Past President and four (4) elected officers. (Each member of the Board of Directors shall have only one vote with the exception of the immediate Past President, who shall have not have a vote). The Director of the Division of Federal-State Relations of the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture-Food Safety Inspection Service, the U.S. Department of Homeland Security and the representative from the Canadian Health Protection Branch and the Canadian Food Inspection Agency shall serve as advisors to the Board, but shall not have a vote.

BYLAWS:

ARTICLE IV - OFFICERS AND BOARD OF DIRECTORS

Section 4. Appointed representatives of the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture-Food Safety and Inspection Service, a Canadian advisor to represent both the Health Protection Branch and the Canadian Food Inspection Agency, and a representative from the U.S. Department of Homeland Security shall serve as advisors to the Board of Directors, but shall not have a vote.

ARTICLE V - EXECUTIVE COMMITTEE

There shall be an Executive Committee composed of the Association's officers, three (3) elected directors, the immediate Past President and a representative of the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture-Food Safety and Inspection Service, U.S. Department of Homeland Security, and a Canadian advisor to represent both the Health Protection Branch and the Canadian Food Inspection

Agency. The chairman shall have the authority to act on behalf of the Board of Directors and make appointments. Composition of the Board of Directors shall be as prescribed in the Association's By-Laws.

ARTICLE VIII - EXECUTIVE COMMITTEE

Section 5. The Executive Committee shall include the Directors of the Federal-State Relations of the Food and Drug Administration, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture-Food Safety Inspection Service, the U.S. Department of Homeland Security, and the advisor from the Canadian Health Protection Branch and the Canadian Food Inspection Agency, but they shall not have a vote in the proceedings.

2004 RESOLUTIONS

ASSOCIATION OF FOOD AND DRUG OFFICIALS

RESOLUTION NUMBER 1

Submitted by: AFDO Seafood Committee

Date: May 12, 2004

Concerning: Imported Uncertified Shellfish

Whereas, the harvesting, processing and distribution of uncooked shellfish are regulated by the states and five foreign nations, Canada, Chile, Mexico, Korea and New Zealand, under the strict standards of the National Shellfish Sanitation Program (NSSP); and

Whereas, shellfish from countries not produced in accordance with the NSSP under a Memorandum of Understanding with the Food and Drug Administration are termed “uncertified” and are prohibited by state laws and regulations from being sold in the States; and

Whereas imported uncooked shellfish from non-MOU countries present a significant public health and food security risk; and

Whereas the Association of Food and Drug Officials (AFDO) recognizes the contribution of the Interstate Shellfish Sanitation Conference (ISSC) to food safety; and

Whereas the ISSC has recently issued a resolution requesting the Secretary of Health and Human Services formally address this issue; therefore be it

Resolved, that AFDO support the ISSC in its effort to control imported shellfish, and similarly recommend that the Secretary of HHS initiate action to prevent the importation of non-MOU, uncooked shellfish into the United States; and be it further

Resolved, that AFDO encourage and support the FDA and industry efforts to identify safe “cooked” shellfish from non-MOU countries that are not regulated under NSSP, but are frequently imported for further processing. The criteria used for determining “cooked” product should be consistent with AFDO’s 2003 resolution #2, i.e., shellfish that have been sufficiently heat-processed to eliminate

all aerobic pathogens, and to be prominently labeled as “cooked”; and be it even further

Resolved, that AFDO support the ISSC’s requests that the FDA coordinate a meeting of the appropriate parties to discuss state and federal cooperative interventions which may address the import problem.

RESOLUTION NUMBER 2

Submitted by: Food Security Task Force

Date: May 18, 2004

Concerning: 50-State Food Security Meeting

Whereas, Homeland Security Presidential Directive 7 requires the Department of Homeland Security to develop an integrated National Plan for Critical Infrastructure and Key Resources Protection to outline national goals, objectives, milestones and key initiatives by December 17, 2004; and

Whereas, the above mentioned plan shall include a strategy to identify, prioritize and coordinate the protection of critical infrastructure and key resources, including how the Department intends to work with State and local governments, the private sector and foreign countries and international organizations; and,

Whereas, AFDO has taken the initial steps toward generating such a plan by establishing a task force which is actively engaged in the development of a “National Food Security Project” based on the principle of a public-private partnership between the food industry, academic institutions and government agencies at all levels; and

Whereas, AFDO believes that a 50-State Food Security Meeting designed to bring together individuals on the national, state and local levels responsible for protecting the various segments of our interconnected and interdependent food supply is a critically needed step in developing a National Food Security Project and for influencing our ability to maximize the collective resources of all stakeholders in protecting our food supply; and

Whereas, the goal for the 50-State Food Security meeting will be to achieve the following outcomes:

- Develop a consensus of what a unified national food and agriculture security strategy should be
- Identify the roles, responsibilities, resources and needs of the stakeholders
- Identify obstacles to the implementation of the strategy
- Achieve commitment and full support from meeting participants
- Establish public-private workgroups and a national coordinating body to follow up on action items
- Establish a timeline for completion of project phases.

Therefore, be it

Resolved, that AFDO ask the Department of Homeland Security (DHS), USDA and FDA to support the concept of a National Food Security Project and a 50-State Food Security meeting by committing available resources to assist in the development and completion of this meeting; and be it further

Resolved, that the meeting be utilized to form a national food security strategy for addressing terrorist threats and incidents involving the food supply; and be it further

Resolved, that AFDO pledges to work with all supporting agencies, stakeholders or associations to hold this meeting and in developing a national food security strategy.

RESOLUTION NUMBER 3

Submitted by: CASA

Date: May 2004

Concerning: Concerning Childhood Obesity

Whereas: A new study by the HHS' Centers for Disease Control and Prevention (CDC) reveals that poor diet and inactivity are about to become the leading preventable cause of death among Americans, causing close to 400,000 deaths annually; and

Whereas, CDC estimates that 64% of all Americans are overweight, including more than 30% classified as obese, and about 15% of children and adolescents aged 6-19 are overweight, almost double the rate of two decades ago; and

Whereas, the American Dietetic Association has stated that 50% of all children aged 2 to 18 years eat less than one serving of fruit a day; and

Whereas educators agree that teaching healthy eating and exercise habits in early childhood will encourage healthier lifestyles in adulthood and research has shown that lifelong eating habits and tastes are learned in infancy; and

Whereas, on March 12, 2004, HHS Secretary Tommy Thompson unveiled FDA's strategy to help reduce obesity with an overall plan, but one that does not target children and adolescents, who are at greater risk of health-related problems concerning the likelihood that obesity will be carried into adulthood; and

Whereas, an effective educational program for children and adolescents is needed and should focus on such areas as:

- School officials helping to educate and encourage healthier meal choices.
- Education campaigns to teach portion control and a more balanced diet.
- Education on the types and range of foods that promote the above.
- Networking with the Federal Trade Commission (FTC) to encourage manufacturers to design advertising campaigns geared to children to promote healthier choices.
- Encouragement of physical activities like sports participation, walking, biking, and the discouragement of "couch-potato/computer game" lifestyles.

Therefore, be it

Resolved that CASA express strong concern to AFDO regarding the alarming obesity problem in this country, with its' many associated serious health problems, and ask AFDO to concur and to convey our mutual feelings to FDA and USDA; and be it further

Resolved that CASA request AFDO to urge FDA and USDA to assign a high priority to the specific problem of obesity in children and to the rapid development of a comprehensive educational program covering infants to adolescents.

RESOLUTION NUMBER 4

Submitted by: CASA

Date: May 2004

Concerning: Consumer Food Safety Labeling of Hot Dogs or Franks

Whereas, surveys of display cases and bulk sales in retail markets throughout the country have indicated the presence of conflicting and contradictory safety and handling information for packaged meat sausage type products, including products commonly referred to as hot dogs, franks, wieners, sausages and wursts; and

Whereas, traditional use and handling instructions have been in place for fully cooked and ready-to-eat products posing no food safety concern, as well as proper heating or cooking information prior to consumption for product not fully cooked; and

Whereas, due to the perishable nature of these products as a potentially hazardous food, label instructions for safe handling of the unopened products will consistently inform the consumer to keep the product refrigerated during storage; and

Whereas, current labeling for only nine (9) of twenty (20) products surveyed indicated that the product was labeled as fully cooked; and

Whereas, instructions for preparing these products for food service ranged from no instructions, to instructions for heating and serving only, and finally to specific temperatures under specific conditions for specific times; and

Whereas, these products which resemble each other (fully cooked or not), being labeled with different preparation instructions, present a confusing and potentially dangerous situation for product mishandling and confusion by the consumer; and

Whereas, the review and regulation of these products within retail food establishments by local or state food safety regulatory personnel is done on the basis of the manufacturers' labeling information and instructions; and

Whereas, contradictory labeling that fails to meet established retail food safety practices will only add to confusion within the food service industry regarding proper handling requirements;

Therefore, be it

Resolved that CASA recommend that AFDO support the development of a consistent labeling format and wording for these products by the U.S. Department of Agriculture, that will provide uniform food safety and handling instructions for similar products, cooked or raw, which are consistent with good public health practice and which address the food safety concerns associated with such products.

AFDO BOARD RECOMMENDATION:

Although the AFDO Board agrees with CASA on this important issue, the Board recommends in lieu of adoption of this resolution that the issue be made a charge to the Meat & Poultry Committee, working closely with CASA, to resolve these issues.

Membership voted at Business Meeting to accept the recommendation of the Board of Directors.

RESOLUTION NUMBER 5

Submitted by: AFDO Laboratory, Science & Technology Committee

Date: June 21, 2004

Concerning: Formation of a National Food/Agriculture Laboratory Committee

Whereas, state agriculture control laboratories are responsible for a broad range of food and agriculture-related analytical activities; and

Whereas, state agriculture control laboratories participate in a number of different associations, and consequently lack a unified voice and identity; and

Whereas, this fragmented system makes it difficult to coordinate and communicate with and among the nation's food and agricultural control laboratories; and

Whereas, food/agriculture protection and defense necessitate improved communication and coordination with associations, agencies, and regulators of food and agriculture products.

Therefore, be it

Resolved, that AFDO supports the creation of a National Food/Agriculture Laboratory Committee that will represent all state agriculture control laboratories; and be it further

Resolved that AFDO supports a vision and mission for this Laboratory Committee, as follows:

Vision: To be the national committee on technical, scientific, and policy issues, representing State Agriculture Control Laboratories to associations, agencies, and regulators of agriculture and food products.

Mission: To provide a voice and leadership for state agriculture control laboratories, this committee will:

- Create a virtual association that helps build community within the body of state agriculture control laboratories, by leveraging Web-based technology for communication and collaboration;
- Provide a mechanism for sharing methods, expertise, and other analytical resources throughout the system;

- Provide a mechanism to identify and rapidly communicate important issues throughout the nation's network of member laboratories;
- Interface directly with associations and government entities on technical, scientific, and policy issues related to laboratory analysis, farm-to-table; and
- Act as a conduit for the solicitation and allocation of additional national resources in support of state agriculture control laboratories, to build laboratory capacity and capability in the areas of emergency response, research, training and development, and food safety, and issues important to the protection and defense of the nation's food supply.

MINUTES OF THE BOARD OF DIRECTORS MEETINGS

Post-Conference Meeting June 18, 2003 Chicago, IL

The meeting was called to order by President Christopher Wogee at 11:50 a.m.

Board Members present: President Wogee, Shirley Bohm, Al Bugenhagen, Sharon Chard, John Lattimore, Marion Fuller, Al Ondis, Denise Rooney, Doug Saunders, Ralph Stafko, Cameron Smoak, and Jim Waddell.

Guests included: Bill Brooks-Journal Editor, Claudia Coles-WAFDO President, Steve Steingart-CASA President, Dan Smyly-Associate Committee Chair, Brenda Holman-Drugs and Devices Chair, Glenda Lewis, and David Read.

President Wogee provided opening remarks which included correspondence from the Second Harvest organization and the proposed MOU with AFDO. The issue of concern with the MOU was liability exposure for AFDO. President Wogee concluded in the discussion that he would review the letter and MOU again and advise Second Harvest of the Board's concern. A copy of the original letter and the MOU will be sent to board members.

President Wogee outlined his goals for AFDO during the coming year. The goals included:

- 1) Increase membership to greater than 1000.
- 2) Provide quality training with low travel costs for attendees.
- 3) Promote and develop more partnerships with FDA like the ORAU MOU.
- 4) Develop international outreach to encourage Mexico and the European Union to participate at a level on par with that of Canada.

President Wogee made the following Executive Committee appointments:

- 1) Brenda Holman to co-chair the FDA Centennial 2006 Task Force.
- 2) Paul Tierney and John Tilden to co-chair the Bio-Terrorism/Counterterrorism Initiative. This work group will consist of one member from each affiliate, FDA and USDA. This work group will develop a meeting for state organizations to address this initiative and report to the board in November concerning the meeting location and possible funding from USDA.
- 3) Establish a work group to develop a food safety program using North Carolina's program as a template. This work group would be part of the States Helping States grant and consist of Joe Corby, Doug Saunders as co-chairs and Jim Austin, John Lattimore, Denise Rooney, Cameron Smoak, Dan Sowards, and Chris Wogee as members.

MINUTES OF THE BOARD OF DIRECTORS MEETINGS 51

- 4) President Wogee did not appoint a representative to the International Association of Fish Inspectors nor authorize attendance to their annual Congress in October in Amsterdam. He referred the matter to Seafood Committee Chair Marion Fuller for further information.
- 5) President Wogee announced the appointment of the following Executive Committee members as follows: Joe Corby as Director of Public Policy, Dan Sowards as Training Advisor, and Betsy Woodward as Advisor to the Board.

Ralph Stafko reported on the expansion of the Lab Workshop to include bio-security capabilities and funding from APHIS. Speakers to include representatives from the White House, Office of Homeland Security and CDC.

Ralph Stafko discussed in limited detail the FSIS Final Rule on Listeria and the performance standard.

Al Bugenhagen distributed the proposed budget for FY2003-2004. A motion was made, seconded and passed to approve the budget.

Al Bugenhagen discussed the recommendation from the audit report concerning the bonding of Shirley Bortner as check signer. A motion was made, seconded and passed to obtain a \$100,000 bond for both Shirley Bortner and Al Bugenhagen as authorized signers of AFDO checks.

President Wogee discussed committee charges as follows:

- 1) Food Committee – no change
- 2) International Government Relations – want closure on Certificates of Export
- 3) Laws and Regulations Committee – Charge #4 to be withdrawn, rewritten and resubmitted to Board
- 4) Seafood Committee – Marion Fuller to review and provide summary to Board concerning industry response to California Emergency rule. This summary will be for information only.
- 5) Membership Committee – develop rules for a contest to identify a brand for AFDO (i.e., Coke is the Real Thing). Top three will be recommended to Board at Spring Meeting for selection of winner. Dan Smyly to contact Larry Eils for trademark issues. The submitter of the winning brand will be awarded full funding to the 2004 Annual Conference.

President Wogee discussed changing the name of the Food Committee to the Food Safety Committee.

President Wogee also discussed the “*News and Views*” disclaimer and that Shirley Bohm will communicate to the editor of “*News and Views*” the finalized disclaimer.

Sharon Chard provided the Canadian report, which included discussion of the following:

52 Association of Food and Drug Officials

- 1) SARS Outbreak: Reactions, Issues, Shortcomings
- 2) West Nile in Canada
- 3) Anthrax on a ship destined for Canada
- 4) Relaxed marijuana laws

Jim Waddell discussed the development of a nationwide consumer complaint program. Jim discussed the possibility of turbo EIRs and eSAP's ability to support this program. Jim Waddell is to provide a summary of the program to President Wogee for discussion at the Spring Board Meeting.

Jim Waddell discussed the likelihood of Gulf oysters being reshipped and being relabeled as from another source and the California regulation to ban Gulf Coast oysters.

Dan Smyly provided the names of the following four individuals to serve for three-year terms on the AFDO Endowment Foundation Board: Gale Prince, John Young, William Sveum and Ken Tabor.

A motion was made, seconded and passed to accept these nominations for three-year terms on the Endowment Foundation Board. Dan Smyly further provided that John Young and Larry Eils will co-chair this foundation board.

Doug Saunders provided the AFDOSS affiliate report which included the Annual Conference being held in New Orleans in Spring 2004 and the news that AFDOSS contributed \$2000.00 to the Endowment Foundation.

Al Ondis provided the CASA Affiliate report, which included the Annual Conference to be held in Pittsburgh, and local arrangements for the 2004 AFDO Conference, also in Pittsburgh. Al also reported a CASA membership of 1300.

John Lattimore provided the MCAFDO Affiliate report, which included the Annual Conference in Lincoln, Nebraska. John also reported a contribution from MCAFDO to the Endowment Foundation.

President Wogee provided the NCAFDO Affiliate report which included the annual meeting in October 2003 and a drug training seminar, also in October 2003.

Claudia Coles provided the WAFDO Affiliate report, which included a September 2003 meeting in Reno, Nevada, and three training seminars.

Al Bugenhagen and Sharon Chard provided the NEFDOA Affiliate report, which included the April 2004 annual meeting in Albany, NY, and the change from two meetings per year to one. Albany, NY, has also been submitted as NEFDOA's choice for the 2006 AFDO Annual Conference.

MINUTES OF THE BOARD OF DIRECTORS MEETINGS 53

Shirley Bohm discussed the possibility of scholarships to attend the annual conference from other organizations such as NRA and the International Food Safety Council Educational Foundation. John Lattimore and Shirley Bohm are to investigate the availability of scholarships and a post-conference workshop with retail food service topics including bioterrorism.

Denise Rooney discussed the 2004 Annual Conference in Pittsburgh and 2005 Conference in Kansas City.

A motion was made, seconded and passed to adjourn at 2:40 p.m.

**AFDO Board of Directors Meeting
November 2, 2003
Double Tree Hotel, Rockville, MD**

The Fall AFDO Board of Directors Meeting was called to order by President Christopher Wogee at 8:05 a.m. on November 2, 2003. Present were: President Wogee, Marion Aller (nee Fuller), Richard Barnes, Denis Blank, Shirley Bohm, Colin Broughton, Al Bugenhagen, Joe Corby, Barbara Hruska, William Kreuger, John Lattimore, Al Ondis, Denise Rooney, Doug Saunders, Cameron Smoak, Ralph Stafko, Paul Tierney, James Waddell, and Betsy Woodward.

Invited guests included: Doug Archer (Guest, University of Florida); Bill Brooks, AFDO Journal Editor, Ken Hohe, AFDO Newsletter Editor; Dan Smyly, Chairman of AFDO Associate Committee; and Dan Sowards, AFDO Training Advisor.

President Wogee's opening remarks included updates on the recent AFDO conference calls (Grants and Biosecurity).

The minutes of the June 18, 2003, meeting were distributed. The minutes were amended by Dan Smyly with the change of John Young to co-chair the Endowment Foundation and Larry Eils to co-chair Associate Membership. A motion was made, seconded and passed to accept the minutes as amended.

President Wogee discussed the status of the following action items:

Representation on the Board from the regulatory community for drugs and devices. Board members representing this group include President Wogee, Barbara Hruska and James Waddell. President Wogee will liaison with the Drug and Device Committee.

The Board agreed to put on a retail food workshop in conjunction with the National Restaurant Association Educational Foundation. The Foundation will contribute a grant for \$5,000 to help defray costs. Shirley Bohm and John Lattimore were assigned to develop a pre- or post-2004 conference workshop addressing Listeria controls and active managerial controls.

The status of the NFSS brochure was discussed. Doug Saunders indicated the brochure was in progress and not yet completed.

The Uniformity Task group was identified as in need of new and replacement members.

Cameron Smoak discussed the Ad Hoc Audit Committee report from Steve Steinhoff. In response to this report the workgroup consisting of Cameron Smoak, Shirley Bohm, Denise Rooney, Al Bugenhagen, Steve Steinhoff and Marion Aller was formed to establish the verification of internal controls. The

report indicated all recommendations of the “Internal Control Audit” have been implemented. A motion was made, seconded and passed to accept the audit workgroup report as amended.

Discussion of the enhancement of the AFDO web site and the anticipated funding to supplement the cost was led by William Kreuger. This discussion concluded with a motion, seconded and passed to table this issue until more information is available.

Richard Barnes provided a report for FDA DFSR. His report included the reduction of DFSR’s budget, the non-availability of small conference grants and noted the focus on food safety is being shifted to food security. He further advised that the AFDO White Paper would be discussed in detail during the meeting with FDA on Tuesday, November 4, 2003.

Doug Saunders and Betsy Woodward discussed the current status of pending National Uniformity Legislation and the potential impact on state regulatory authority. Betsy Woodward indicated she would develop an AFDO uniformity action plan with a focus on education. The education fact sheet will include what states do in relation to food security and food safety utilizing the data from the state survey and identifying what will be lost at the state level if the legislation is approved in its current form. A meeting in Washington, DC, between NASDA, AFDO, ASTHO, etc., will be initiated to develop a white paper addressing the pending uniformity issues.

Cameron Smoak discussed the interim committee reports. A motion was made, seconded and passed to accept all interim committee reports as submitted unless the report requires action by the Board.

The following committee reports required action by the AFDO Board:

Alumni Committee – Charge 9

Shirley Bohm is to co-chair workgroup for this charge. A motion was made, seconded and passed to maintain the current affiliate rotation cycle for the AFDO educational conferences.

Food Committee – Charge 5

A motion was made, seconded and passed to request FDA and USDA to review AFDO’s Recall Guidelines for agreement, recommend modifications and make recommendations at the Spring Board Meeting.

Meat and Poultry Committee

Committee Chair John Arnold requested to communicate with Ralph Stafko, Richard Barnes and Shirley Bohm concerning the use of carbon monoxide on fresh meats.

Dan Smyly advised the Board the AFDO Endowment Foundation would be developing a strategic plan for the Foundation.

Doug Archer from the University of Florida reported on the status of the CSREES Grant and Retail Food Processing Advisory Grant with information for variances. A motion was made to apply for additional grant funding with the University of Florida for development of additional consumer advisories and posting of these advisories on the AFDO web site.

Doug Archer also discussed NFSI's Recall Manual Guidance for small- and medium-size firms and a possible Train-the-Trainer in January 2004 for industry, state and local attendees. The discussion also included the consolidation of the FDA, AFDO and University of Florida's Recall Guidance Manuals. A motion was made, seconded and passed to have AFDO partner with the University of Florida to consolidate the three recall manuals into one harmonized model with use of footnotes for specific requirements.

Denise Rooney provided a Seafood Alliance update. The alliance will be meeting in February and AFDO will be represented by President Wogee and one other member.

Dan Sowards provided a report from the Dietary Supplement workgroup. His report included an AFDO "Train-the-Trainer Course" addressing dietary supplement regulation proposed for the Fall of 2003 in Kansas City. He also reported of the possibility of combining this training with training (on the FDA proposed GMPs for dietary supplements for 2004, which might be held in the Spring of 2004. He also expressed some problems in communicating with FDA since John Foret is on a detail with the Department of Homeland Security. Richard Barnes volunteered to look into the matter.

Bill Brooks provided a report from the workgroup charged to look into combining the Newsletter and the Journal into a magazine publication. A motion was made, seconded and passed to disband the workgroup, combine the "*News and Views*" with "*E-News*" and keep the Journal. A motion was made to establish a workgroup to work specifically with the Journal publication, its format, method of distribution and possible combination with other publications, i.e., *News and Views* and *E-News*. This workgroup will be co-chaired by Steve Steinhoff. Ken Hohe provided an update on the next copy of "*News and Views*" scheduled for publication in January 2004.

President Wogee discussed the AFDO liaison representatives to other organizations. A motion was made, seconded and passed to delete an AFDO liaison representative to the "Egg Safety Initiative" organization since that group had completed its mission.

Al Bugenhagen presented the July 1, 2003 to present budget status. The report included moving some of the funds into an account which will produce a return. A motion was made, seconded and passed to accept the report.

Denise Rooney provided an update of activities in the AFDO office. The discussion included sending the AFDO "*E-News*" to all affiliates and maintaining a "members only" section. This action may encourage affiliate members to join AFDO.

Colin Broughton provided the Canadian update, which included the following topics:

SARS – 45 deaths

West Nile – the dry summer may have reduced the incidence of infection

Anthrax Scare – prove negative

Marijuana – movement is being made to reverse current legislation

Natural Health Products Regulations

It's Your Health – a publication and web site

Marion Aller discussed the progress of the 2004 Annual Education Conference. The discussion included split sessions for food and drug/device issues.

Bill Kreuger discussed the possibility of another post-conference laboratory workshop. The discussion included the length of the overall conference including the pre- and post- conference workshops.

The meeting adjourned at 5:35 p.m.

Board of Directors Meeting with USDA

The Board meeting resumed at 9:00 a.m. on November 3, 2003, at the USDA offices. Present at this meeting were Board members: President Wogee, Marion Aller, Denis Blank, Shirley Bohm, Colin Broughton, Al Bugenhagen, Joe Corby, Barbara Hruska, William Krueger, John Lattimore, Denise Rooney, Doug Saunders, Cameron Smoak, Ralph Stafko, Paul Tierney, Jim Waddell and Betsy Woodward.

Guests included: Bill Brooks, Dan Sowards, and John Hoffman.

The meeting was opened with a welcome from Ralph Stafko, USDA, FSIS advisor to AFDO.

Dr. Garry L. McKee, Administrator, FSIS, provided an FSIS update and addressed current topics of interest. Dr. McKee's presentation addressed strategic goals at FSIS, new and improved training functions, transition to public health focus in FY2003 and FY2004, FY2004 proposed joint activities with states, and FY2005 focus on public health with the establishment of regional training centers in Dallas, Atlanta and Philadelphia.

Dr. McKee's presentation was followed by an AFDO update from AFDO President Christopher Wogee. President Wogee's remarks included a proposed 50 states bioterrorism/counterterrorism meeting, ORA-U training, a consolidated recall guidance document, carbon monoxide use in packaged meats and outreach activities to Mexico and the European Union.

Phillip Derfler, Assistant Administrator, FSIS, discussed pathogen reduction policy developments. The pathogens addressed in his presentation included *E. coli* 0157:H7, *Listeria monocytogenes*, *Salmonella* and *Campylobacter*. Mr. Derfler advised that the recent risk assessments by FDA identified deli meats at retail as the highest risk for *Listeria monocytogenes* and USDA was developing a plan to address this issue.

Mr. Loren Lange, Deputy Assistant Administrator, followed with a presentation on Pathogen Reduction Policy Implementation. This presentation focused on the pathogen sampling program, which is risk-based. The current program calls for up to 8,000 samples of intact ready-to-eat deli meats for *Listeria monocytogenes*.

Dr. D.W. Chen, Acting Assistant Administrator, FSIS, discussed current counterterrorism activities in the office of Food Security and Emergency Preparedness, FSIS. His presentation included discussion of critical infrastructure sectors,

interagency food workgroup, food shield, Food Emergency Response Network (FERN), Incident Command Structure (ICS) and support of a 50 states meeting addressing biosecurity/counterterrorism.

Doctors David Goldman and Faye Bressler, Office of Public Health & Science, FSIS, addressed epidemiology and other outbreak response issues. Their discussion included a consumer complaint monitoring system of all complaints to FSIS concerning products which the agency has responsibility for. The discussion also included activities of the Public Health and Epidemiology Liaisons (PHELS).

Dr. Armia Tawadrous, Director, Recall Management Division, FSIS, discussed recall activities and the establishment of District Recall Officers (DRO). Currently nine states have signed the recall MOU with FSIS and Dr. Tawadrous encouraged that all states participate by signing this MOU.

Dr. Kenneth Peterson, Executive Associate for Regulatory Operations, FSIS, discussed the recall classification and the relationship with public health. Dr. Peterson also encouraged states to sign the recall MOU and to contact him with concerns or obstacles involving the MOU.

Mr. Raymond Saunders, Director, Budget Division, provided a FY2003 budget and FY2004 continuing resolution update.

Ms. Barbara Robinson, Deputy Administrator, Transportation and Marketing Programs, AMS, provided an update on the USDA's Organic Certification Program. Her presentation included the certification of certifying agents, their responsibilities and auditing of the certifying agents.

Ms. Margaret Venuto, Food Safety and Food Science Program, CSREES, discussed grant availability under the NIFSI program. A total of approximately \$14.2M/year is distributed to 40 award recipients with the maximum single award of \$600,000.00.

Ms. Gerri Ransom, Microbiology Division, Office of Public Health and Science, provided an update for the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). NACMCF is currently reviewing FSIS baseline study protocols, criteria for refrigerated shelf life based on safety, scientific criteria for redefining pasteurization and microbiological performance standards for raw meat and poultry.

CDR Lynn Hodges, Office of the Administrator, FSIS, provided information on FSIS training activities, plans and opportunities for state employees. Her

presentation included activities at USDA FSIS Food Safety Virtual University, an annual training survey and the five training centers. FSIS has set the goal to train 2,400 FSIS employees during 2004 and to appoint five additional trainers.

Dr. Patrick McCaskey, Executive Associate for Laboratory Services, Office of Public Health and Science, FSIS, provided an update of laboratory activities. Assisted by William Kreuger, Dr. McCaskey discussed ISO 17025 Accreditation, Lab Information and Management System (LIMS), bar coding and the Food Emergency Response Network (FERN).

Robert Tynan, Deputy Director, Office of Public Affairs, Education & Outreach, FSIS, provided an update on activities at the National Advisory Committee on meat and poultry inspection. The committee consists of approximately 16 individuals including Michael Govro, AFDO.

Ms. Susan Conley, Director, Food Safety Education, FSIS, provided an update on consumer education, industry outreach and USDA resources available to states. Her discussion included the USDA Food Safety Mobile, which has visited 55 cities in 25 states.

Ralph Stafko provided a wrap-up to this FSIS/AFDO meeting. The meeting adjourned at 4:35 pm.

Board of Directors Meeting with FDA

The Board meeting continued on November 4, 2003, at the FDA offices in Rockville, MD convening at 8:30 a.m. AFDO Board members present included: President Wogee, Marion Aller, Denis Blank, Shirley Bohm, Colin Broughton, Al Bugenhagen, Joe Corby, Barbara Hruska, William Krueger, John Lattimore, Al Ondis, Denise Rooney, Doug Saunders, Cameron Smoak, Paul Tierney, Jim Waddell and Betsy Woodward.

Guests included: Bill Brooks, Karen Deasy (for Art Liang), John Hoffman, Dan Sowards, and Steve Steingart (CASA President).

Opening remarks were provided by John Taylor, Associate Commissioner of Regulatory Affairs, FDA, and Steve Solomon. The discussion included continued support for training, liberty shield, budget issues, contracts with states and the loss of various grant funding.

A facilitated session to address "AFDO's White Paper" was to follow. After a brief discussion with the facilitator, Wayne Matthews, it was concluded the end results of the session were already identified in the white paper.

With the facilitated session concluded, President Wogee reconvened the Board meeting at 10:50 am.

President Wogee provided discussion of the need for an advisor from the Department of Homeland Security (DHS) be added to the AFDO Board. A motion was made, seconded and passed to have a member from DHS added to the AFDO Board as an advisor. Until otherwise informed by DHS, John Hoffman would serve as DHS's advisor.

Denis Blank provided discussion on membership including recruitment, retention, rewards and virtual membership with restrictions and partial rewards. Denis further discussed the development of a logo/slogan contest for AFDO and to advertise it in the "*News and Views*" as well as ask the affiliates to include it in their newsletters.

The contest will be judged by three members of the Membership Committee. A motion was made, seconded and passed to award the winner of the contest \$300 in AFDO credit for use as registration at the annual conference, an Endowment Foundation contribution and/or membership dues. President Wogee will send out the details of the contest and selection criteria in the next *e-News*.

President Wogee discussed solicitation and modification of grants. A motion was made, seconded and passed to charge the Administration Committee to draft a policy dealing with application for new and existing grants, modification of grants and clarifying notifications to the Board.

Denise Rooney is to send a proposed travel policy to all Board members for comment.

Dan Sowards discussed the need for a special award for those that may no longer qualify for the Wiley Award. A motion was made and seconded that the Board presents Dan Smyly with the outstanding service award to include the number of years of service to AFDO. A motion to table this motion until Wednesday was made, seconded and passed.

The Board meeting was adjourned for lunch, to reconvene with a presentation by Sherri Dennis.

Sherri Dennis, FDA, provided a presentation on FDA's Listeria risk assessment. Her discussion included background for the risk assessment, exposure assessment, hazard characterization, risk characterization and "what if" scenarios.

Joe Levitt provided a CFSAN update with emphasis on bioterrorism and counterterrorism agenda. His presentation also included obesity issues, lawsuits for obesity, health claims and security issues/security clearances.

Lou Carson provided an update on FDA's Bioterrorism Regulations. His presentations included the interim final rule, the December 12, 2003, effective date for registration and prior notice.

62 Association of Food and Drug Officials

Carl Sciacchitano provided an update on eLEXNET. His discussion included the use of eLEXNET as the electronic communication vehicle for FERN. He also indicated his willingness to address attendees at the affiliate conferences.

The panel of Agnes Kivuvani, Larry Cook and David Graves provided an update on Electronic State Access to FACTS (eSAF). Their discussion included the current pilot program with Texas and Rhode Island, and the addition of 8-10 more states (40 users) in February 2004. The program will be fully operational December 8, 2003.

Patrick McGarey and Tina Harper provided a legislative update addressing various bills with effects on FDA programs. The discussion also included pending budget issues.

Closing remarks were provided by Paul Raynes with adjournment at 4:40 pm.

AFDO Board of Directors Meeting (reconvene)

The Fall AFDO Board Meeting was called to order by President Christopher Wogee at 8:05 a.m. on November 5, 2003. Present were: President Wogee, Marion Aller, Denis Blank, Joe Corby, Barbara Hruska, William Krueger, John Lattimore, Al Ondis, Denise Rooney, Doug Saunders, Cameron Smoak, Ralph Stafko, Paul Tierney, Jim Waddell and Betsy Woodward.

Guests were: Joel Blackwell (Guest Lecturer), Bill Brooks, Karen Deasy (for Art Liang), Ken Hohe, Phillip Petry (Liaison from AAFCO), Dan Sowards, and Steve Steingart (CASA President).

A presentation by Joel Blackwell addressing "Lobbying for Non Profit Organizations" dealt with how non-profit organizations can effectively lobby and still maintain the IRS non-profit classification. His presentation included IRS regulations and definitions. The presentation concluded with the tools needed to effectively lobby. The tools needed include: professional staff, media, money, grass roots and someone on the inside who can make it happen.

After the presentation and Board discussion, it was determined a follow-up conference call in mid-December will be scheduled to discuss possible lobbying/education for AFDO.

Phillip Petry, AAFCO Representative, presented an update of activities at AAFCO. His report included announcement of two AAFCO meetings, one in January and one during August 2004.

Karen Deasy presented the agency update for CDC. Her presentation included information on a one-day meeting with ASTHO with focus on food safety/security.

Steve Steingart, CASA President, provided a local arrangement report for the 2004 AFDO Conference, Pittsburgh, PA. A motion was made, seconded and passed not to have a Monday night event during the 2004 Conference.

Denise Rooney presented the profit/loss statement for the 2003 AFDO Conference and proposed raising the conference registration fee to ensure all costs are covered. A motion was made, seconded and passed to keep the registration fee the same, eliminate discounted rates, i.e., group rates, but raise the rate for the Wiley Banquet and Burditt Luncheon.

Joe Corby reported on the draft Cured, Salted and Smoked Fish, GMP, AFDO Model Code and the draft *Listeria monocytogenes* Control Manual, which is referenced in the Model Code. The draft code with the *Listeria monocytogenes* Control Manual is to be sent to the Laws and Regulations Committee for review. A motion was made, seconded and passed authorizing Joe Corby to pursue an initiative for *Listeria monocytogenes* training.

Barbara Hruska provided the WAFDO Affiliate Report. Her report included the WAFDO Annual Conference, increase in WAFDO's membership and the awarding of \$2000.00 in scholarships. Her report also included that Mike Govro had been awarded the Orlen Wiemann Award.

Al Ondis provided the CASA Affiliate Report. His report included CASA membership at 1,200 and the CASA Conference in May 2004.

Doug Saunders provided the AFDOSS Affiliate Report. His report included the upcoming meeting scheduled for New Orleans in March and AFDOSS's contribution to the Endowment Foundation.

John Lattimore provided the MCA Affiliate Report. His report included the upcoming meeting scheduled for Lincoln, Nebraska, and the establishment of a web site.

Paul Tierney provided the NEFDOA Affiliate Report. The report included a strategic planning meeting scheduled for December 2003, the Annual Conference May 2004 in Albany and a pre-conference bioterrorism meeting.

Bill Kreuger provided the NCAFDO Affiliate Report. The report included the NCAFDO web site, drug/device/lab workshops and the Annual Conference in October 2003 in Minnesota.

Doug Saunders reported on the proposed 50 States Meeting and requested approval of AFDO's National Food Security Project Vision Statement. He reported on the meetings with ASTHO and NRA where support for the 50 States Meeting was discussed. Funding sources for the 50 States Meeting were discussed including possible ethics issues of accepting funding from non-government organizations.

President Wogee appointed James Waddell as AFDO's liaison to eLEXNET.

It was announced the Spring Board meeting will be in San Antonio, Texas, on March 15 and 16, 2004.

Betsy Woodward is to develop an AFDO Uniformity Action Plan.

The meeting was adjourned at 11:55 a.m.

**Spring Board of Directors Meeting
San Antonio, Texas**

Monday, March 15, 2004

Present: Chris Wogee, Marion Aller, Richard Barnes, Denis Blank, Colin Broughton, Joe Corby, Barbara Hruska, Bill Krueger, John Lattimore, Denise Rooney, Doug Saunders, Dan Sowards, Cameron Smoak, Jim Waddell and Betsy Woodward.

Invited guests: Al Almanza (for Ralph Stafko), Jim Austin, AFDO Technical Grants Administrator, Ben Jones, President AAFCO, Karen Deasy (for Art Liang), and John Hoffman (by telephone).

Due to the absence of Al Bugenhagen, Chris Wogee appointed Barbara Hruska to act as Secretary to the AFDO Board for this meeting.

A motion was made, seconded and passed to adopt the minutes of the January 28, 2004, Conference call as amended.

A motion was made and seconded and voted upon and passed to adopt the Membership Strategic Plan on the January 28th Board Teleconference.

Denise Rooney distributed the Budget Report and explained that, overall, AFDO's income and expenses are consistent with projections.

The 50 State Meeting relative to developing a national food security strategy was discussed extensively and John Hoffman, DHS Advisor to AFDO Board, joined the discussion via phone. Doug Saunders reported on behalf of the project task force. FDA, CDC, and FSIS are all represented on the task force. A draft agenda for the proposed 50-State Meeting was distributed. The strategy for the meeting is based upon the use of "workgroups" to develop deliverables. Currently the task force is attempting to secure funding to support travel of state representatives to the meeting. The tentative dates for this event are August 16-20, 2004. John Hoffman is exploring options for potential sources of federal funding. The AFDO Board expressed concern regarding the need to secure a commitment of funding before efforts can be completed regarding final planning for this event. A hotel must be secured by April 15, 2004. It is estimated that \$500,000 is needed to fund this event.

A motion was made, seconded and passed to draft a change in bylaws to provide for the position of DHS Advisor to the AFDO Board. This proposed change will be mailed to AFDO members for their vote. The AFDO office will handle the logistics to accomplish this task.

Richard Barnes provided comments on the AFDO White Paper. Key issues are related to funding and to sharing of data. Four and one half million dollars are

available from FDA to states for BT/CT lab-related issues. FDA can only expend money one year at a time unless Congress changes the budget authority. Electronic Access to FACTS (eSAF) is in production and will be expanded to additional states. FDA can offer “option” years to grants; however, all states do not want this option. FDA requested that AFDO identify priorities for the agency and FDA hopes that AFDO can indicate if these are also priorities for the states. FDA requested that the AFDO Board members participate in FDA/AFDO Board priority projects such as eLEXNET. FDA reviews the level of participation.

The Membership Committee solicited recommendations for AFDO “brands” and presented five final suggestions for consideration by the Board.

Betsy Woodward provided information relative to national uniformity legislation and she also distributed the “National Uniformity of Food Acts” notebook, which includes: AFDO press release, impacts for food safety, newsletter article, state analyses, congressional correspondence, state laws preempted, evaluation of impact, history of HR 2699, sponsors/summary, impact on Food, Drugs and Cosmetic Act, unresolved questions, and miscellaneous correspondence. AFDO intends to provide a presentation at each affiliate meeting regarding this issue and they will personalize the presentation for each audience. The Board agreed that AFDO should disseminate a one-page position statement.

Funding for AFDO was discussed. Several grants are ending or will end soon that have been providing resources to offset a portion of salaries associated with the AFDO office.

The Board recognizes the need to examine (and update if necessary) AFDO’s strategic plan.

Denise Rooney indicated that she wishes to reduce her work hours to four 9-hour days per week and she indicated that the AFDO office could lose another position. Discussion included potentially restructuring the AFDO Executive Director position and perhaps giving consideration to Denise’s suggestion of a possible job sharing approach. This could encompass Denise transitioning portions of her responsibilities to another individual. The ideal candidate could possibly be a person retired from state regulatory work. Denise indicated that she was receptive to the Board’s wishes regarding potential changes. She also stated that her intent was to be very transparent regarding her future plans and that she is entertaining potential options directed toward a transition into retirement.

A motion was made, seconded and passed to allow Denise Rooney to work four 9-hour days per week with Fridays off. She will also retain 100% of her benefits with a 10% decrease in salary because her hours of work were decreased by 10%.

Committee Reports were discussed and in part included:

MINUTES OF THE BOARD OF DIRECTORS MEETINGS 67

- A structure will be developed to assist with nomination and selection of the Associate Award.
- A charge will be developed to have the Education and Training Committee work with the AFDO Training Advisor.
- A new committee chair is being sought for the Food Committee and suggestions should be sent to Cameron Smoak via email.
- Food Committee charges not completed will be carried over to next year.
- The use of international speakers for the AFDO Annual Conference is usually dependent upon resources provided to cover their expenses and AFDO needs to plan for this. It will be discussed at the June Board meeting.
- The Board is not approving Charge 3 of the International and Government Relations Committee and will request that the recommendation be rewritten and presented at the June Board meeting.
- A new committee chair is being sought for the Laboratory, Science and Technology Committee and the committee will be asked to provide recommendations in their report for the Board's review in June.
- Efforts will be focused on implementation of the Membership Committee's recommendations to welcome new attendees and all other attendees throughout the entire annual conference.
- A new committee chair is being sought for the Alumni Committee.
- Charge 9 of the Retail Food Committee Report will be continued to June 2004 to incorporate changes from CFP.
- Charge 6 of the Seafood Committee Report will be completed in June 2004.
- Concern was expressed regarding the publication of the *AFDO Journal*. The editor has indicated that it has been very difficult to obtain articles for the journal.
- Dan Sowards, Joe Corby, Denise Rooney, John Lattimore, and Bill Krueger will look at issues relative to AFDO communication tools including use of the *AFDO Journal*, potential of a magazine, etc. The workgroup will be asked to report to the Board by June 2004.

68 Association of Food and Drug Officials

- A motion was made, seconded, and passed to accept all committee reports as amended except the following: Drugs and Devices; Education and Training; and Laboratory, Science and Technology.
- Cameron Smoak, Dan Sowards and Chris Wogee will provide assistance to the Drug and Device Committee until June 2004.
- Cameron Smoak will request that the Education and Training Committee and the Laboratory, Science and Technology Committees add responses in the "Recommendation" category and the Board will review and vote on acceptance.
- The Board agreed to have a meeting during the annual conference for committee chairs and it will include an explanation of committee report generation.

Ben Jones gave the Association of American Feed Control Officials (AAFCO) report. This is an international association. Current issues include: best management practices for feed manufacturing; enforcement of dietary supplement requirements associated with animal feed; feed curriculum; commerce; and BSE. They are in favor of a specified risk material ban. AAFCO would like to see the labeling exemption for pet food removed.

The Seafood HACCP training report indicated that 17,536 students have been trained in 946 courses.

A pilot course was held in Rockville for the CDC "States Helping States" Grant titled "Applications of Basics of Investigation and Inspection". The train the trainer course will be held the week of March 22, 2004, in Dallas, TX. Funding for travel of affiliate trainers to other states in the affiliate region may be provided through the grant. It is under negotiation at this time.

A steering committee has worked on 6 retail food guidance documents and the Board was asked to give final approval of the documents. The Board was directed to review documents and they will be discussed on a future Board conference call. Dan Sowards explained that the input requested is an overall view of the information.

FDA indicated that the agency would conduct a course on dietary supplements in 2005. They would like representation from state Attorney General offices and it will be directed at taking enforcement actions. AFDO will not conduct AFDO training on this topic; however, it will work with FDA regarding the 2005 course.

AFDO hopes to have a Drug and Device Workshop associated with the 2005 AFDO Conference.

MINUTES OF THE BOARD OF DIRECTORS MEETINGS 69

AFDO has worked with Penn State on an educational proposal to address listeria.

The Food Advisory Committee provided comments regarding methyl mercury and basic recommendations were generated.

Tuesday, March 16, 2004

Present: Chris Wogee, Marion Aller, Richard Barnes, Denis Blank, Colin Broughton, Joe Corby, Barbara Hruska, Bill Krueger, John Lattimore, Denise Rooney, Doug Saunders, Dan Sowards, Cameron Smoak, Jim Waddell, and Betsy Woodward.

Invited guests: Al Almanza, USDA, Jim Austin, AFDO Technical Grants Administrator, Karen Deasy, CDC, and Eric Hoffman, Datastream.

Potential nominations for AFDO Vice-President were discussed. Recruitment has been a challenge due to the amount of travel and the impact upon the president's regular employment responsibilities.

Doug Archer would like to hold a meeting to discuss merging the 3 recall manuals (FDA, UFL and AFDO).

AFDO has \$193,000 in reserves and consideration was given to funding travel associated with the annual conference. It was suggested that perhaps USDA could be contacted regarding potential funding. A motion was made, seconded and passed to allow up to \$20,000 from AFDO reserves to fund this and the details will be established by the Strategic Plan workgroup.

AFDO has received a request for an electronic copy of the Food Emergency Pocket Guide. AFDO currently sells hard copies for \$8 each. AFDO's goal is to have this available to all field inspectors and the need exists to make it available in a form that can be loaded onto laptops. A motion was made, seconded and withdrawn to provide for AFDO to sell the electronic version for \$4 each to government officials through the use of a signed agreement. Jim Austin and Karen Deasey will gather more information regarding the sale and licensing of this document. Information will be forwarded to the Board for future action.

Eric Hoffman with Datastream provided information relative to web design. The capacity for AFDO will be tripled. The project is also intended to help local affiliates to pass and share information. Funding for this initiative is approximately \$30,000 of grant dollars. AFDO recognizes the importance of giving consideration to future Web-based needs of the organization.

A discussion included future investments in AFDO that could include defining and filling additional positions. They might include: two full-time positions directed toward grant procurement and web content and 2 intern positions associated with the 50-State Meeting. The intent is to make AFDO a "go to"

70 Association of Food and Drug Officials

agency. The group agreed to charge the Strategic Planning group with developing and making a recommendation to the Board within the next 30 days.

The Canadian update included information relative to: new government, creation of an agency of public health, therapeutic access strategy, smart regulation, emergency preparedness, Internet pharmacies, nutrition, multi-use medical devices, single-use medical devices, GMPs for medical devices, clinical trials, adverse reaction reporting.

Several changes have been made to the annual AFDO conference agenda. A BSE presentation will be added and the EU Perspective will not be possible. Dr. Crawford will likely give the FDA keynote. It was agreed that the pre-conference workshop be marketed to industry.

The CDC report included: funding of cooperative agreements to examine state and local capacity relative to investigation of foodborne disease; team training/EPI Ready to fill gaps at the local level; partnering with FDA on food safety task forces; CDC bioterrorism grants; and a food net data publication.

FDA's update addressed the following: personnel changes (Dr. Crawford is Acting Commissioner); priorities (imports, MDUFA, BSE, registration, bioterrorism); budget reductions; interim final rules on BSE; Maryland tabletop exercise (CDC not participating, USDA and FDA are observers only); limited non-regulatory travel; DFRS reduced personnel due to budget; food safety and security task forces will be increased to \$7,000 per year on 3-year grants.

USDA update included: personnel changes; new consumer safety guidelines on Web; BSE and SRMs.

Status of grants:

- States Helping States—last year of the grant, state survey will be repeated, food security objectives will be included in the final year application, food security booklet could be revised for version 2, web site enhancements proposed, learning exchange under consideration. Jim Austin requested that the Board review proposed suggestions for the grant and respond to him with comments.
- FDA Food Code Adoption Project: project promotion will be reduced.
- The Exempt Slaughter Grant has been completed.
- Two potential Listeria grants have been submitted to USDA.
- Consumer Complaint Monitoring System is a potential grant project for a national uniform system. Several AFDO members are serving on a

MINUTES OF THE BOARD OF DIRECTORS MEETINGS 71

project committee for this USDA/FSIS project. The committee is in the process of attempting to define the scope and boundaries of the complaint system.

AFDOSS will hold a conference in New Orleans March 28-31, 2004.

WAFDO is in the process of planning the annual educational conference to be held in San Diego September 11-15, 2004. The theme is "Fostering Cooperation Between Agencies and Industries." A workshop addressing safe water systems for drugs and devices may be held during the conference.

MCA will meet in Lincoln, Nebraska, on May 4-6, 2004.

NCAFDO conference will be held in Minneapolis in October, 2004. Much effort is currently being directed to the redesign of NCAFDO's web site.

Concern was expressed regarding the number of surveys distributed by AFDO including surveys from AFDO committees.

Several conference calls for the Board will be scheduled prior to the annual conference to address some items prior to the Board meeting that will facilitate more time for face-to-face discussions of other issues.

Enhanced information will be provided at the committee chair meeting at the AFDO annual conference. It will include more direction for committee report writing and facilitation of meetings. The committee chair meeting will be expanded to accommodate this need from 4:30-5:30 p.m.

The Board gave consideration to restructuring duties of the AFDO Vice-President and AFDO President Elect. A protocol has been developed that addresses the planning of the annual conference. It will be provided to the new AFDO Vice-President.

"Brands" were presented to the AFDO Board for consideration. A vote of the Board occurred and the results will be forthcoming.

The fall AFDO Board meeting was scheduled tentatively for November 14-17, 2004, and Denise, Cameron, Marion, Denis and the Advisors will have a conference call to discuss the structure of this meeting.

The afternoon session was divided into groups addressing strategic planning and membership. Summaries of these groups were not a part of the Board minutes. The Board Meeting was adjourned.

**AFDO Board Meeting
9:00 a.m. June 19, 2004
Pittsburgh, PA**

Present: President Chris Wogee, Cameron Smoak, Marion Aller, Al Bugenhagen, Barbara Hruska, John Lattimore, Denis Blank, William Krueger, Doug Saunders, Jim Waddell, Al Ondis, Paul Tierney, Shirley Bohm, Dan Sowards, Joe Corby, Betsy Woodward, Denise Rooney, Dan Smyly, Bill Brooks, Art Liang, Ralph Stafko, Colin Broughton, Paul Raynes and John Hoffman.

The meeting was called to order by President Wogee.

The minutes of the June 3, 2004, conference call were reviewed. A motion to approve the minutes as amended was made, seconded and passed.

Marion Aller provided an update of the Annual 2004 Conference. Discussion included low attendance, financial issues and changing the date of future conferences.

Terri Ribble, Conference Direct, provided a presentation of what her company could provide to AFDO involving negotiations with hotels of future conference sites. Thus service can be provided with no cost to AFDO with the hotel paying Conference Direct.

A motion was made, seconded and passed to try to obtain the services of Conference Direct based on endorsement by John Young that approval is OK for AFDO.

A motion was made, seconded and passed to compensate Terri Ribble \$1000.00 for her services relevant to the 2004 conference.

John Young reported on the endowment foundation and the reappointment of trustees Daniel Badia, Richard Silverman and Fred Hegele and the appointment of Robert Klepinski and Virginia Edleman. A motion was made, seconded and passed to approve the trustee appointments.

Al Bugenhagen reported on budget status for fiscal year 2003/2004. A motion was made, seconded and passed to accept the budget report.

Betsy Woodward reported on the National Uniformity Bill, HR 2699. This bill currently has 141 sponsors. Betsy's discussion included the impact on state food safety programs should it pass and become law.

John Lattimore and Marion Aller reported on the recall workgroup efforts with the University of Florida to consolidate recall manuals. A motion was made, seconded and passed that once the recall workgroup has approved the new manual, the workgroup can allow the AFDO logo to be used for the new manual.

Dan Sowards and Cameron Smoak provided discussion on the submission of committee reports and the short time to review the reports prior to making them available to the Board. Suggestions to assist with submission of reports included a board member to liaison with each committee.

Denise Rooney provided three policies for consideration by the Board.

- Annual Conference Locations
A motion was made, seconded and passed to adopt the proposed policy as amended. The amendments included the hosting affiliate submitting cities for the conference to the Board for approval.
- Conference Program Planning and Oversight Workgroup
A motion was made, seconded and passed to adopt the proposed policy as amended. The amendment included the addition of CDC and DHS representatives to the workgroup.
- Annual Conference Speaker Expenses
A motion was made, seconded and passed to adopt the proposed policy as amended. The amendment included the Vice President as program chairperson.

Dan Sowards, Training Director, reported on proposed training to be sponsored by FSIS. The train-the-trainer training will focus on bioterrorism, to be held in all 15 FSIS districts with a target date of September 2004.

Paul Raynes provided an update on proposed dietary supplement training to be provided by FDA to states.

William Krueger reported on the proposed National Food/Agriculture Laboratory Committee and its role for laboratories and associations. A motion was made, seconded and passed to endorse the concept of a National Food/Agriculture Laboratory Committee.

Chris Wogee discussed the AFDO Strategic Plan 2004 update. A motion was made, seconded and passed that the Board will add an additional day to the Fall Board Meeting to discuss, update or modify the AFDO Strategic Plan. A motion was made, seconded and passed to have this meeting with the aid of a facilitator.

Bill Brooks provided an update on the *AFDO Journal*.

Dan Sowards reported on the resolutions policy. A motion was made, seconded and passed to accept the proposed change in the numbering system within the policy.

74 Association of Food and Drug Officials

Dan Sowards reported on the four resolutions received for consideration.

- **Resolution #1 Imported Uncertified Shellfish**
A motion was made, seconded and passed that USFDA coordinate a meeting of the appropriate parties to discuss state and federal import issues.
- **Resolution #2 Food Security Task Force**
A motion was made, seconded and passed to recommend approval of this resolution.
- **Resolution #3 Concerning Childhood Obesity**
A motion was made, seconded and passed to accept as amended. The amendment included the deletion of “including lower consumption of high caloric foods including snack foods for” with the addition of “and” in its place.
- **Resolutions #4 Consumer Food Safety Labeling of Hot Dogs or Franks**
A motion was made, seconded and passed that the AFDO Board agrees with CASA that this is a very important issue and should be referred to the AFDO Meat and Poultry Committee to resolve and make recommendations.

The Board of Directors recommended that the Laboratory, Science and Technology Committee draft a resolution (# 5) for Board review prior to the posting deadline.

John Hoffman reported on Department of Homeland Security including a proposed three-day 50-state training/outreach meeting addressing “National Infrastructure Protection Plan, Food and Agriculture”.

Colin Broughton provided the Canadian update.

Art Liang provided the CDC update.

William Krueger provided an update on “Data-Stream” and that a demo would be available during the conference.

Respectfully submitted,

Alfred E. Bugenhagen
July 6, 2004

2004 BUSINESS MEETING MINUTES

June 23, 2004
Pittsburgh, PA

President Wogee called the meeting to order. He announced the successful results of the Silent Auction and the Endowment Fund contributions. Over \$3,000 was raised from the Silent Auction and over \$11,000 was pledged to the Endowment Fund. He also announced the election results — Charlene Bruce, Vice President; Steve Steingart, Director-at-Large; and John Lattimore, Secretary-Treasurer.

A motion was made, seconded and passed to approve the minutes from the 2003 Business Meeting as printed in the proceedings issue of the *Journal* and posted on the bulletin board during the conference.

A motion was made, seconded and passed to approve the 2004 Committee Reports.

A motion was made, seconded and passed to approve the 2004 Resolutions 1, 2, 3 and 5.

A motion was made, seconded, and passed to extract Resolution 4 and to accept the AFDO Board's recommendation that the resolution be referred to the Meat and Poultry Committee as a new charge for additional study.

The President called upon the Secretary-Treasurer to give a summary report on the current financial status of the organization. A motion was made, seconded and passed to approve the Treasurer's Report.

No old business was brought forth for discussion.

President Wogee passed the gavel to incoming president Cameron Smoak, who thanked Mr. Wogee for all of his efforts during the past year.

2003-2004 ADOPTED MODEL CODES AND GUIDELINES

Food Emergency Pocket Guide

The Food Emergency Pocket Guide is intended for use by field staff in food regulatory programs. It is a “ready reference” to deal with some of the common — and uncommon — emergencies dealt with by food regulators. These emergencies can be due to foodborne illness outbreaks, natural disasters (floods, fires, hurricanes, etc.), and accidental contamination of food supplies (truck & train accidents, building explosions, etc.) as well as willful acts of contamination.

There are sections of the guide that consist of advice for consumers; these sections may also be useful reference material for regulators.

Cured, Salted, and Smoked Fish Establishments: Good Manufacturing Practices

This model code was first adopted by the Association of Food and Drug Officials (AFDO) in June 1991. The code was developed by the AFDO Food Committee under the direction of Dan Sowards, Food Committee Chair, in response to an expressed need for nationwide uniform guidance for regulating establishments that cured, salted, and smoked fish. Such guidance had not existed since the repeal of smoked fish regulations, previously contained in Title 21 of the Code of Federal Regulations. The primary focus of the Code was for the control of *Clostridium botulinum* Type E — an organism commonly found in the marine environment that has caused outbreaks of botulism in these types of fishery products.

The June 1997 revision incorporates the use of terminology to define mandatory requirements and identifies all temperature requirements in Centigrade as well as Fahrenheit formats.

The most current revision is designed to integrate within this model code the requirements of 21 CFR Part 123 Fish and Fishery Products and the recommendations from the “*Listeria monocytogenes* Control Manual,” produced by the Smoked Seafood Working Group of the National Fisheries Institute (NFI) and the National Food Processors Association (NFPA). This revision was completed through the AFDO Seafood Committee, Marian Aller, Chairperson.

Guidelines for Exempt Slaughter and Processing Operations

These guidelines address the inspection of exempt slaughter and processing operations of amenable species, game animals, and exotic animals. They are intended to provide a national standard for these operations, and therefore sought to fit with the construction of the Federal Meat Inspection Act and the Federal Poultry Products Inspection Act.

The development of the guidelines and of the curriculum was funded and made possible by a two-year cooperative agreement between AFDO and the United States Department of Agriculture.

FINANCIAL REPORT

Association of Food and Drug Officials
Balance Sheet as of June 30, 2004

	Jun 30, 04
ASSETS	
Current Assets	
Checking/Savings	
1001 · CONFERENCE	\$108,936.38*
1005 · CONFERENCE SAVINGS	40,124.80
1010 · GENERAL	71,791.70
1015 · GENERAL SAVINGS	40,124.80
1030 · GEN FUND RES - CASH MGMT	54,480.58
1040 · GEN FUND RES - STRAT PORT	
1041 · General Fund Strat Reserve-Cost	80,607.42
1042 · Unrealized Gain/Loss on Fund	-12,289.76
Total 1040 · GEN FUND RES - STRAT PORT	68,317.66
1070 · SCHOLARSHIP	
1072 · Scholarship - Cost	57,173.47
1071 · Unrealized Gain/Loss on Invest	-11,744.24
Total 1070 · SCHOLARSHIP	45,429.23
Total Checking/Savings	320,268.77
Total Current Assets	320,268.77
Fixed Assets	
1701 · Office Equipment	49,300.79
1710 · Accumulated Depreciation	-28,830.67
Total Fixed Assets	20,470.12
TOTAL ASSETS	<u>\$340,738.89</u>
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Other Current Liabilities	
2100 · Payroll Liabilities	-495.20
Total Other Current Liabilities	-495.20
Total Current Liabilities	-495.20
Total Liabilities	-495.20
Equity	
3900 · Net Assets	449,396.26
Net Income	774.21
Total Equity	450,170.47
TOTAL LIABILITIES & EQUITY	<u>\$449,675.27</u>

Note: Conference income is received prior to June 30; expenses are recorded and paid in the next fiscal year.

2003-2004 FINAL COMMITTEE REPORTS

The 2003-2004 Final Committee Reports can be viewed on the AFDO web site at <http://www.afdo.org/committeereportsfinal.asp>.

2004-2005 COMMITTEE CHARGES

Administration Committee

Chair: Barbara Hruska, CO Department of Public Health, Denver, CO

Co-Chair: Gary German, FDA, Rockville, MD

Charge 1: Work with AFDO Executive Committee and AFDO Executive Director to develop a five year strategic plan. The strategic plan should be based on the top five to ten priorities for the organization (e.g., food security, training, membership, etc.), and should include recommendations for AFDO office staffing.

Charge 2: Work with AFDO Grant Co-coordinator to provide assistance dealing with grant applications, modification of existing grants and notification to the AFDO Board as needed.

Charge 3: Continue to provide interpretation and guidance relative to the AFDO Constitution and By-Laws.

Charge 4: Provide Board with suggestions and guidance for AFDO web-site enhancement.

Charge 5: Review and recommend changes, if deemed needed, to enhance the AFDO Committee system. Consider the following:

1. Have the Final Committee Reports due no earlier than April 15th, and possibly as late as May 1st.
2. Have the AFDO office send the Final Reports to the Board around May 1st and give the Board members a full 45 days to review the reports and get their comments in to the President.
3. By the AFDO Board Meeting at the Annual Conference, everyone should have read and commented on the reports, and the process of voting (if not already done by teleconference) should not usurp much Board time.

This would accomplish several things:

1. We would not “lose” over two months’ worth of Committee work time.
2. The “flow” from one year to the next would be smoother, and perhaps more real work on the charges would/could get done.
3. The Board members would not be rushed into reading, digesting, and commenting on more than 250 pages of reports in less than a week’s time.

Alumni Committee

Co-Chair: Terry Macaig, Williston, VT

Co-Chair: George Fong, Tallahassee, FL

Charge 1: Work with the AFDO office staff to capture and use alumni information to communicate more efficiently with AFDO alumni by utilizing the enhanced AFDO web site.

Charge 2: Work with each Regional Affiliate and the Membership Committee to track Alumni and develop methods and projects to involve them in AFDO and regional affiliate activities.

Charge 3: Compile a list of Alumni members who would be willing to serve as trainers for AFDO training programs including their area of expertise. Work with AFDO's Training Coordinator to identify training programs that will be provided and trainer needs.

Charge 4: Provide input about subjects for the 2005 Annual Educational Conference. Identify Alumni to the Local Arrangements Committee who are willing to provide support in the planning and during functions of the conference.

Associate Membership Committee

Co-Chair: Dan Smyly, Coca-Cola North America, Atlanta, GA

Co-Chair: Larry Eils, National Automatic Merchandising Association, Chicago, IL

Charge 1: Assist the AFDO President and Board of Directors with the development of position papers, providing comments to rulemaking proceedings and identifying issues that will have an impact on AFDO members as requested.

Charge 2: Survey at least ten top agriculture commodity buying companies to determine their requirements, if any, for certification by a Good Agriculture Practice (GAP) program. Include information as to the level of certification in the food production and distribution chain (e.g., farm, packing, distribution, etc.), the entity providing the certification and the standards used (e.g., USDA, FDA, combination or other).

Charge 3: Provide a Master of Ceremonies for the 2005 Wiley Award Banquet.

Charge 4: Provide topics and/or speaker suggestions that Associate Members would like included in the 2005 AFDO Conference program to the AFDO Vice President & Program Chair. Forward any ideas for workshops, symposiums, etc., for consideration. Participate in the development and administration of the Annual Educational Conference, workshops, symposiums, and other forums as requested by the AFDO President or Board.

Charge 5: Provide articles to be used for the AFDO *e-News* that would be of special interest to Associate Members. Articles might include special activities or accomplishments by members, promotions, employment changes, or new initiatives in areas of concern to AFDO members.

Awards Committee

Chair: Eugene Blake, City of Concord Health Services, Concord, NH

Charge 1: Work with the Affiliates to liaison with their awards committees with the objective of improving communication about, and interest in, AFDO Awards and Scholarships. Also use their assistance in publicizing the availability of AFDO Awards and Scholarships to increase more applicant awareness and application submissions.

Charge 2: Begin the process of soliciting scholarship applications nationwide no later than September 1, 2005, to assure communication of this funding opportunity to the largest possible number of qualified candidates. Additionally, letters should be sent to all Regional Affiliates, along with AFDO's scholarship information, requesting that they provide this information to colleges and universities within their region and publish it in their Affiliate newsletter. Review applications and forward recommendations to the Board for final approval by the due date as established in the AFDO Policy Manual.

Charge 3: Actively solicit applications for the 2004-2005 AFDO Associate Award from members and affiliates. Review nominations and forward recommendations to the Board for final approval by the due date established in the AFDO Policy Manual.

Charge 4: Actively solicit applications for the 2004-2005 AFDO Achievement Award from Affiliates and members. Review nominations and forward recommendations to the Board for final approval by the due date established in the AFDO Policy Manual.

Charge 5: Work with the Media and Public Affairs Committee to produce at least 2 articles for the AFDO *e-News*. The first article should be the congratulatory article for award winners from this year and the second article should be a solicitation for candidates for next year's awards. Work with the *e-News* Editor to agree on a timeframe and deadlines.

Drugs, Devices and Cosmetics Committee

Chair: Larry Upjohn, CA Department of Health Services, Sacramento, CA

Co-Chair: Karen Tannert, TX Dept. of Health, Austin, TX

Charge 1: Monitor and provide feedback to the Board about issues related to consumer concerns, research and regulatory activity associated with drugs, devices, cosmetics and their components. Develop draft comments and position statements as requested to assist the AFDO President in the preparation of official comments and position statements.

Charge 2: Research and develop a good manufacturing practices (GMP) model for cosmetics and a model set of standards for cosmetic ingredients. Cosmetics are increasingly being used with a greater potential for harm. For example, cosmetics are being promoted for use by children, used as skin exfoliates, and permanently applied (tattoos, permanent eye liners, etc.). Cosmetics are also used in body orifices, e.g., mouthwashes, dentifrices, vaginal cleansers, etc. Cosmetics have been contaminated with pathogenic microorganisms. To better protect the users of cosmetics, good manufacturing practices for cosmetics would help assure their quality thus decreasing possible adverse health effects. Standards for cosmetic ingredients would also promote the public health by helping assure that consumers are not exposed to cosmetics that contain ingredients with harmful constituents. Examples for the need for ingredient standards might be that dyes and pigments, especially if they are permanently applied, should contain minimal quantities of heavy metals; herbal ingredients should have microbial limits, harmful ingredient degradation byproducts should be minimized.

Charge 3: Utilizing the conference template provided by the AFDO office, provide the AFDO Vice-President (Program Chair) with topic and speaker suggestions for the drug and medical device portions of the Annual Conference. Work closely with the Program Chair to determine which drug and device issues might be of interest to the entire audience.

Charge 4: Compile a contact list of State and local drug and/or medical device programs within the United States. Provide the list to the AFDO office with the request that the office send each program contact not currently a member of AFDO information identifying AFDO and ways that the organization may benefit them.

Education and Training Committee

Chair: Frank Greene, CT Health Department, Hartford, CT

Charge 1: Work with FSTEAs to develop training and guidance materials for increased security and counterterrorism procedures in food establishments.

Charge 2: Continue to develop and update the education and training portion of the AFDO web site. Review and update posted materials, submit new items, identify new training course information for posting, and submit new links to Web information that will be valuable to AFDO members.

Charge 3: Provide at least 1 article for the AFDO *e-News* encouraging the use of the FDA ORA-U training opportunities.

Charge 4: Evaluate and make recommendations to the AFDO Board on methods to bring quality training to state and local agencies without requiring interstate travel. The review should address available technology, costs of equipment and materials, satellite training courses, interactive computer training, etc. The goal is to bring valuable AFDO training to regulators who may not be able to travel due to budgetary constraints. Recommend current training programs that could be adapted to a format that meets this goal. Consider the possibility of using retired regulatory members as presenters in their respective states.

Field Committee

Chair: Gerald Wojtala, MI Department of Agriculture, Lansing, MI

Co-Chair: David Read, MN Department of Agriculture, St. Paul, MN

Charge 1: Monitor and report to the Board about dynamic and emerging Field issues related to foods, drugs, medical devices and cosmetics.

Charge 2: Provide suggestions to the Education and Training Committee and the AFDO Training Director for any training needs of Field members. Assist with training programs to enhance participation and ensure proper delivery.

Charge 3: Research the need for a national minimum credential requirement for field staff in light of the pressure from industry for field inspection staff to be certified to a set of standards and make suggestions as to how AFDO could work to resolve this issue.

Charge 4: Research and make suggestions as to how AFDO could provide for uniform guidance to regulatory program administrators on issues impacting field activities. Such issues may be as follows:

- (A) Home-prepared foods and “value-added” foods produced at farm level.
- (B) Small volume operations producing acidified foods.
- (C) Cow-share, farm-share, shareholders, etc., trying to circumvent dairy laws.
- (D) Uniform standards between US and Canada concerning pathogen testing for ready-to-eat (RTE) foods at retail level.

Food Committee

Chair: Terri Wenger, Wisconsin Agriculture, Trade & Consumer Protection

Co-Chair: Michael Govro, OR Department of Agriculture, Salem, OR

Charge 1: Monitor and report to the Board about dynamic and emerging issues related to use, concerns, research and regulatory activity associated with foods and food ingredients.

Charge 2: Review and provide the AFDO Board with comments on the Consumer Complaint Monitoring System (CCMS) when the Work Group completes the document.

Charge 3: Assist the AFDO President and Board of Directors with the development of position papers, providing comments to rulemaking proceedings and identifying issues that will have an impact on AFDO members as requested.

Charge 4: Edit and complete the development of standards for the transportation of potentially hazardous foods.

International and Government Relations Committee

Co-Chair: Gary Dykstra, FDA, Atlanta, GA

Co-Chair: Bob Scales, Health Products & Food Branch, Health Canada, Winnipeg, MB

Charge 1: Monitor and report to the Board about dynamic and emerging issues related to uses, concerns, research and regulatory activities associated with imported and exported foods, drugs, medical devices, and cosmetics.

Charge 2: In the interest of increasing transparency of and access to information on foreign government export certification requirements, Federal agency food export certification authorities, and State government certifying authorities: collect data on foreign country import certificate requirements, compile a reference directory that can be used to determine the appropriate agency, with contact information, that issues Certificates of Free Sale, Certificates of Export, and Health Certificates for most common exported products by AFDO member countries, assess the acceptance of the AFDO model food export certificate system by the states and its acceptability by several foreign governments in a pilot study and complete development of the Food Export Certificate web site so that it will be ready to implement for use by all interested parties.

Charge 3: Assist the AFDO Annual Conference Chair in identifying and contacting International Speakers who would address topics of interest to the AFDO membership.

Charge 4: Monitor the current comments and drafts of the World Health Organization's International Health Regulations (IHR) and keep the AFDO Board advised.

Laboratory, Science and Technology Committee

Chair: Reuben Beverly, GA Department of Agriculture, Atlanta, GA

Charge 1: Monitor and report to the Board about dynamic and emerging laboratory and science issues related to foods, drugs and medical devices.

Charge 2: Foster inter-agency communication, collaboration and acceptance by promoting appropriate method validation and reporting of analytical results. Continue liaison with the FDA, USDA, EPA, CDC, DOD Veterinary Services, AOAC International and the Association of Public Health Laboratories in support of these efforts. Encourage participation in the Food Emergency Response Network (FERN). Keep the Board informed of any significant technical or coordination issues.

Charge 3: Participate in developing and adopting of the proposed committee comprising analytical laboratory committees of AFDO, AAPCO, AAFCO, AAPFCO, AOSA and NASDA as directed by the Board. Represent the interests of AFDO within the larger community of State and federal food and agricultural regulatory laboratories. Report to Board on issues related to this effort.

Laws and Regulations Committee

Chair: Guy Delius, Kentucky Department for Public Health, Frankfort, KY

Charge 1: Monitor and report to the Board about dynamic and emerging issues related to changes in laws, regulations, and/or major policies that have an effect on foods, drugs, medical devices, and cosmetics. Such issues are likely to include updates on:

- National uniformity
- Food Security
- Proposed Dietary Supplement GMP regulations
- Biosecurity
- Origin of product labeling
- Product safety regulations and standards
- Genetically Modified Organism regulation and labeling
- Imported product surveillance and restrictions

To complete this charge, the Committee shall also:

- Provide updates for the AFDO *e-News* on the committee's overall progress on one or more of the dynamic or key issues it has worked on. Work with the Board on a subject and timeframe by January 1, 2005.
- If necessary, work with the Director of Public Policy to develop draft position statements when warranted. Work with the Director of Public Policy to define and prioritize the issues and key concerns that the Committee believes warrant development of an AFDO position or Official Comments. Submit recommendations to the Board for consideration. Based on Board action on these recommendations, develop and implement a work plan for development of draft AFDO positions.

Charge 2: Work with AFDO's Executive Director to post information on new laws and regulations on the AFDO web site noting any significant changes to these bills or proposed regulation to the Board immediately. At a minimum, provide summary reports for the fall, spring, and annual Board Meetings.

Charge 3: Track legislation and agency and court interpretations of Federal food safety laws and regulations related to dietary supplements and emerging pathogens. Provide "real time" feedback to the AFDO Executive Committee on the legislation and related issues of interest or importance to AFDO.

Charge 4: Review proposed model codes and guidance documents formulated by any AFDO Committee, Task Force or Working Group for proper structure and format.

Meat and Poultry Committee

Chair: John Arnold, NY Department of Agriculture and Markets, Albany, NY

Charge 1: Monitor and report to the Board about dynamic and emerging issues related to use, concerns, research and regulatory activity associated with meat and poultry.

Charge 2: Work with the USDA, FDA, and managers of State regulatory food programs to clearly identify the authority and rationale for redundant or overlapping activities at specific points along the farm-to-table continuum. This could include, for example, wholesale processing and retail meat operations in one facility, FSIS sampling ground beef in retail food stores, etc. Work to foster a dialogue with the objective of minimizing redundancy and using partnerships to maximize food safety protection in a way that is both effective and efficient.

Charge 3: Work with the Food Safety and Inspection Service's In Distribution Inspection (IDI) staff to develop guidance for retail food inspectors regarding violations of the Federal Meat Inspection Act and Poultry and Poultry Products Act during transportation and retail sale and identify who should be responsible for follow-up for particular types of violations.

Charge 4 Background: Surveys of display cases and bulk sales in retail markets throughout the country have indicated the presence of conflicting and contradictory safety and handling information for packaged meat sausage type products, including products commonly referred to as hot dogs, franks, wieners, sausages and wursts. Traditional use and handling instructions have been in place for fully cooked and ready-to-eat products posing no food safety concern, as well as proper heating or cooking information prior to consumption for product not fully cooked. These products, which resemble each other (fully cooked or not) and are labeled with different preparation instructions, present a confusing and potentially dangerous situation for product mishandling and confusion by the consumer. Instructions for preparing these products for food service ranged from no instructions, to instructions for heating and serving only and finally to specific temperatures under specific conditions for specific times.

Charge 4: Work with The U.S. Department of Agriculture to develop a consistent labeling format and wording for these products that will provide uniform food safety and handling instructions for similar products, cooked or raw, which is consistent with good public health practices and which addresses the food safety concerns associated with these products.

Media and Public Affairs Committee

Chair: Steve Steingart, Allegheny County Health Department, Pittsburgh, PA

Charge 1: Promote, coordinate, and support media coverage of subjects and presenters at the AFDO Annual Educational Conference.

Charge 2: Using the Media Plan outline activities to be implemented to promote and report on the 2005 Annual Conference and submit to the Board for review at the Spring Board Meeting.

Charge 3: Publicize AFDO's activities such as workshops and awards in trade publications and the press. Provide information about AFDO achievements, awards or scholarship winners to the recipients' hometown newspapers.

Charge 4: Work with the Membership Committee to further develop and implement the promotional and informational aspects of programs or information targeted toward new members (e.g., mentoring).

Charge 5: Support the AFDO office staff in development and/or review of marketing materials.

Membership Committee

Chair: Denis Blank, NE Department of Agriculture, Lincoln, NE

Vice Chair: Barbara Cassens, FDA, Alameda, CA

Charge 1: Contact persons interested in AFDO membership as indicated by the AFDO office. Also contact those members who fail to renew membership. Efforts should be directed at recruiting interested persons and retaining current members.

Charge 2: Continue efforts in developing Mentoring concepts within AFDO.

Charge 3: Foster the implementation of the Membership Strategic Plan.

Nominations and Elections Committee

Chair: Chris Wogee, US Department of Commerce, Citrus Heights, CA

Charge 1: Solicit qualified candidates as nominees for the office of Vice President. Develop a slate of candidates for this position. Work with the Executive Director to develop and distribute a ballot to the AFDO membership in accordance with the by-laws and established policies and procedures. Include biographical information for each candidate with the ballot.

Charge 2: In coordination with the AFDO office and at the request of the AFDO Board, schedule any special elections that may be required if an officer vacates a position prior to the expiration of his or her term of office.

Charge 3: Provide articles for *e-News* related to nominations for officers of AFDO and the final results of the election.

Resolutions Committee

Chair: Dan Sowards, TX Department of Health, Austin, TX

Charge 1: Review the resolution process and recommend any needed improvements for the submission, processing, and consideration of resolutions. Work with the Executive Director to incorporate approved changes into the AFDO Policy Manual.

Charge 2: Encourage and solicit resolutions on timely topics from the Regional Affiliates. Recommend improvements that may be warranted to increase the number or quality of resolutions.

Charge 3: Edit and finalize resolutions through consultation with the presenter. Submit resolutions to the Board in accordance with AFDO Policies and Procedures.

Charge 4: Provide one or more articles for AFDO *eNews* related to resolutions adopted by the AFDO membership.

Retail Food Committee

Chair: John Lattimore, TX Department of Health, Austin, TX

Co-Chair: Ellen Laymon, OR Department of Agriculture, Salem, OR

Charge 1: Monitor and report to the Board about dynamic and emerging issues related to use, concerns, research and regulatory activity associated with the preparation, holding, and selling of food at the retail level.

Charge 2: Research the issue of the sale of live poultry at retail and compile list of states that allow this activity and include copies of their law and regulations. List pros and cons of live poultry sales.

Charge 3: Update the entire AFDO Food Code Pocket Guide and solicit input from the AFDO Field Committee.

Charge 4: Write basic guidelines to manage food safety risks unique to food service operations that employ a voluntary workforce.

Charge 5: Implement the Food Committee's 2003/2004 workgroup's following suggestions:

- 1) Survey retail food program managers to identify who is participating/not participating in FDA's Retail Food Regulatory Program Standards program, why/why not, and benefits/barriers to participation;
- 2) Identify contact persons or "subject matter experts" willing to provide assistance to other jurisdictions either enrolled or considering participation in the standards program; and
- 3) List the contact persons or subject matter experts on the AFDO web site.

Charge 6: Identify training, guidance, interpretations, etc., about the Food Code that will provide resources for field staff and then work with the AFDO office to provide these documents or links on the AFDO web site for a new "Food Code Central." Work with the AFDO office to review the organization of Food Code information posted on its web site.

Seafood Committee

Chair: Jennifer Tebaldi, WA Department of Health, Olympia, WA

Co-Chair: Al Ondis, FDA, Baltimore, MD

Co-Chair: Rick Barham, VA Department of Agriculture, Richmond, VA

Charge 1: Monitor and report to the Board about dynamic and emerging issues related to use, concerns, research and regulatory activity associated with seafood.

Charge 2: Serve as the liaison between AFDO and the Seafood HACCP Alliance, the Interstate Shellfish Sanitation Conference (ISSC), the National Food Safety System Project (NFSS) and other seafood safety organizations and projects with respect to seafood issues of mutual concern to those organizations. One issue of concern that could be addressed with this group is that of “overboard waste disposal” and how it affects food safety.

Charge 3: Assist in the continuing enhancement of AFDO’s web site relative to seafood issues. Identify appropriate references, policies, laboratory methods, and standards that could be posted on the AFDO web site. Also identify useful links with other web resources.

Charge 4: Continue to solicit input and develop draft comments for submission to the AFDO Board of Directors on the FDA’s Seafood Inspector Certification program.

ASSOCIATION OF FOOD AND DRUG OFFICIALS

NEW PUBLICATION OFFERINGS

Food Emergency Pocket Guide

Today's food safety threats bring new challenges to the food system in the United States. The food industry, scientists, and regulatory agencies have developed extensive expertise in food safety – protecting the food supply against unintentional food contamination.

After September 11th, we recognized a dramatically increased potential for terrorist threats and unprecedented new challenges associated with ensuring the *security* of our food supply – protecting against *intentional* food contamination. Terrorist threats could involve familiar agents the system is already looking for or can quickly respond to; but there is also the possibility of new, unfamiliar, or unexpected agents to be used in food and food systems.

The challenge we face is to build on the food safety systems we have in place by ensuring timely implementation of effective risk reduction practices, by being prepared to respond to an event, and by having plans in place to quickly recover after the incident.

Guidelines For Exempt Slaughter And Processing Operations Training Program Manual

The guidelines were developed as a result of a grant to AFDO from the United States Department of Agriculture, Food Safety and Inspection Services (USDA/FSIS).

Exempt slaughter and processing operations are, in many cases, unlicensed or unregistered and the limited oversight of these operations may present a gap in our current food safety and security system in this country.

The scope of these guidelines is comparable to those accepted practices recognized for a meat processing establishment. We believe that adopting and implementing these guidelines, where there is little or no oversight of such activities, will eliminate a void in a national goal of a seamless food safety and security system.

Visit www.afdo.org/publications
to obtain the Publications Order Form.
25% Member Discount