

Food and Drug Administration Alumni Association

Serving Those Who Have Served

The Annual Report
8th Edition



2009 Achievement Highlights

Our thanks go to the many people who volunteered their time in support of FDAAA programs and operations over the past year. The FDAAA also appreciates the support of the following organizations:

- Covington & Burling (www.cov.com)
- EAS Consulting Group, LLC (www.easconsultinggroup.com)
- Food and Drug Administration (www.fda.gov)
- Food and Drug Law Institute (www.fdli.org)
- Temple University School of Pharmacy (www.temple.edu/pharmacy)
- Personal Care Products Council (formerly The Cosmetic, Toiletry, and Fragrance Association) (www.personalcarecouncil.org)

We especially thank Lois Beaver for preparing the 2009 Annual Report. We hope you enjoy it!

In preparing this publication, every effort has been made to ensure that the information is as up to date as possible and its accuracy verified. However, due to the ever-changing nature of some portions, there may be instances where information as presented is incorrect. Readers are encouraged to report incomplete, inaccurate, or new information to Edward Steele (esteele@easconsultinggroup.com).

Message from the Chair of the Board of Directors

In this, my final message as Board Chair, I wish to briefly take stock of our decade-long journey together as an Association and also peer over the horizon for a glimpse of our future.

As many of you know, the idea for an FDA Alumni Association literally began on a piece of paper 10 years ago. In the years since, the dream of a few has materialized into reality for hundreds. From a small band of organizers based in the Washington, DC area, our membership has steadily grown and should soon eclipse the 1,000 mark. We can take great pride in how far we have come and feel very optimistic about the tremendous growth potential in the years ahead.



*Elizabeth D. Krell, Ph.D.
Chair*

What began with a kick-off luncheon in Gaithersburg, MD has become an organization whose reach extends to the far corners of our country and indeed the world. Here at home, we continue to provide financial aid to the next generation of public health leaders through academic scholarships. We remain engaged with FDA leaders on ways the agency can usefully leverage the substantial knowledge and experience of our members and, in turn, how FDAAA can legally support FDA's mission and funding. And we are exploring establishment of regional or state-based chapters to give our members outside the immediate DC area more opportunities to get involved.

Internationally, our outreach extends to countries including Jordan, China and governments in Africa as they work to strengthen their public health and regulatory systems.

All in all, this is an impressive record of service for any organization, especially one as young as ours!

So as I prepare to turn over the Board chairmanship, I thank you for the honor of serving you and our Association. I also want to commend you on all the hard work and support you've invested in the FDAAA and to offer two challenges.

First, be proactive as individuals in spreading the word to fellow FDA alumni and colleagues. I challenge each of you to recruit at least one new member over this next year so that our membership rolls double or more.

Second, get involved in some aspect of our Association: governance, committee activities, domestic or international projects, etc. Growing an organization is more than just expanding the membership base; it involves expanding opportunities to serve and the social impact of our service.

In keeping with these challenges, let me close with a final thought from former Supreme Court Justice Oliver Wendell Holmes.

"What lies behind us and what lies before us are tiny matters compared to what lies within us."

Remarks from the President



*F. Alan Andersen, Ph.D.
President*

The FDA Alumni Association is alive and well, and living in ... just about everywhere! We've left the 800 member number in the dust and are working toward 900. And we're located in Europe, in Asia, and across the USA. We're experienced in administration, we have technical expertise in every program area at FDA, and do we know inspections and all that field stuff? You bet!

Our tag line – Serving Those Who Have Served – continues to be our focus. We serve FDA alumni by providing communications, holding functions, listing opportunities, etc., all the stuff you will read about in our annual report. Serving those who have served also takes the form of helping those who still are serving, the current staff at FDA.

One of my favorite examples is the invitations that come in on a steady basis to CFSAN from a foreign government or NGO to have someone travel to a foreign destination and help train another government's inspectors or teach industry groups about food safety. And this would be a good thing to do to improve food safety. For you retirees, I gotta tell you, the budget for foreign travel hasn't improved since you were there! So, here we are with a need and FDA can't fill it. FDA Alumni Association alumni members often can fill that need. These efforts to link alumni with opportunities meet the needs and interests of alumni, AND they have a very tangible benefit to the current staff at FDA.

From the very outset, and in spite of the name that only says "alumni," we have included the opportunity for current FDA employees to join as associate members. Many of you have heard me say: "alumni in training." Our intent is to inform and facilitate communications between and among current and past employees of the Agency so that we can continue to undertake efforts that meet our alumni and associate members needs.

As we look forward to 2010, I'm hoping that we can parlay the efforts we made to focus on those members outside the Washington area with the "field subcommittee" of the communications group into something bigger.

So, stay tuned and stay engaged. For alumni, it's a good feeling that what you know and the insights you've developed over a career can be of help to support the Food and Drug Administration. For associate members, you ground us in the present - always a good thing.

FDAAA's Mission

The Association's core mission is to help alumni stay in touch with the issues of the day facing the FDA and support the agency's public health mission through expertise— and experience-sharing, training and outreach opportunities. Membership is open to the thousands of FDA alumni and current employees nationwide. FDAAA's activities designed to support this mission are:

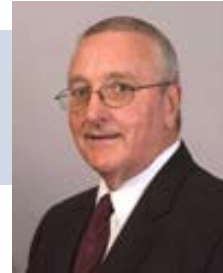
- Periodic educational seminars and conferences on major public health and FDA issues
- Expertise-sharing opportunities with FDA
- Outreach programs designed to stimulate interest in FDA employment
- Consultations with national health authorities on regulatory strategies and programs
- FDAAA Updates, providing members with frequent email communications
- FDAAA Website with links to FDA, and other informative sites
- Membership directory

The Year in Review—Highlights of FDAAA’s Achievements

Improved Communication with Membership

Through informative FDAAA Updates, President Alan Andersen ensures that FDAAA members are aware of Association activities, events, new members gained and generally what is happening. This year, over two dozen information packed emails were distributed to members.

Under the able direction of Edward Steele, Chair of the Communications Committee, the website was revised to better reflect the lively activities and accomplishments of the FDAAA.



*Edward Steele
Chairman Communications Committee*



*Robert Becker
Chairman Photo Subcommittee*

A Photo Subcommittee led by Robert Becker was formed to set guidelines and maintain the photo album page on the FDAAA website.

Country-wide communication was established through an active Field Subcommittee, headed by Darryl Brown, with field section representatives Elaine Messa, Brenda Baumert and Diana Kolaitis. In August, section representatives sent introductory letters to field alumni inviting their participation in FDAAA. At the end of the year, holiday greetings served as a reminder of the Association’s continuing interest in FDA alumni in the field.



*Darryl Brown
Chairman Field Subcommittee*



*Elaine Messa
West Section Representative*



*Brenda Baumert
Central and Southeast Section
Representative*



*Diana Kolaitis
Northeast Section
Representative*

Increased International Outreach

FDAAA's Activities Committee established a subcommittee, the FDAAA International Network (FDAAA IN), to act as a clearinghouse to provide consultation with foreign regulatory authorities on the establishment and operations of regulatory programs. The Subcommittee is co-chaired by Florence Houn and Zili Li. The FDAAA IN co-sponsored a successful pilot regulatory science educational seminar on vaccine development, anti-infective products and new treatments for cancer for personnel of the Chinese State Food and Drug Administration in Beijing. At the August 2009 Asia Pacific Economic Cooperation Life Sciences Innovation Forum in Singapore, the FDAAA mission was presented to regulatory authorities, industry and academia seeking to strengthen support for innovation that improves health and economic outcomes. In March 2010, FDAAA IN made a presentation at the 2nd African Regulators Conference in Johannesburg, South Africa describing the FDAAA as a resource for regulators in the area of medical product development and oversight.



*Florence Houn
Treasurer*



Zili Li



Continued Support of the FDAAA Scholarship Fund

To help commemorate the centennial of the Pure Food and Drugs Act, the FDA Alumni Association established a scholarship fund to encourage training in regulatory and quality issues. Based on its outstanding training programs and its relationship with the FDA, Temple University School of Pharmacy's Quality Assurance/Regulatory Affairs graduate program was selected for this scholarship.



Scholarship award recipients in 2009 were Troy Timbrook, Megan Daly and Paul Mouris. Troy took his BS in Biology to work at AmeriFlora'92 and on to Boehringer Ingelheim Roxane Inc. Upon completion of his MS at Temple, Troy hopes to move out of QA and into DNA submissions. Megan's education path started with a 1998 Associate degree in Biological Science, was followed by an Associate in Applied Science in 01 and culminated with a BS in 05. During this time she worked as a lab tech, a clinical analyst, a private lab analyst, a hospital lab chemist and finally in the Microbiology Dept. of a drug company. Upon completion of Temple's QA/RA graduate program Megan wished to focus on pharmaceutical microbiology. Paul served 6 years in the US Navy before attending the University of Connecticut. In 2003 he graduated summa cum laude with a Doctor of Pharmacy degree. The past six years Paul has been an FDA Investigator focusing on the drug industry. Completion of Temple's QA/RA master's program will help him toward his goal "to become an even better FDA Investigator".

For further information on the FDAAA Centennial Scholarship see the FDAAA website. Criteria and information on application for the scholarship is on the Temple University School of Pharmacy website (www.temple.edu/pharmacy_QARA.ns).

Held FDAAA Board of Directors Meetings

When they met on October 15, 2009, the FDAAA Board of Directors took a number of actions including: approving a policy establishing term limits of Board members; fostering transparency in Association business practices; establishing a lifetime membership category; approving the acquisition of organizational liability insurance; agreeing to sponsor activities outside the Washington area; requesting an improvement of promotional materials to attract FDA employees; and directing the exploration of legitimate funding for educational activities, especially those associated with the international network.

At its winter meeting on January 25, 2010, the Board welcomed Mr. Joseph Baca to fill the Board position held by John Taylor who left to rejoin FDA. Ms. Carrie Cannady became the Chair of the Awards Committee. Other actions of the Board included: directing consideration of budget enhancement options; re-visiting the possibility of forming state-based chapters; reviewing implications of potential involvement in lobbying activities; approving the dissemination of FDAAA promotional materials; and establishing the agenda for the Board meeting to be held on April 22, 2010.



Joseph Baca



Carrie Cannady

Held Luncheons to Learn What's Happening at FDA



Nancy Myers
Activities Co-Chair



Anne Marie Finley
Activities Co-Chair

Co-Chairs Nancy Myers, Anne Marie Finley along with the members of the Activities Committee organized several luncheons featuring various FDA leaders who illuminated the changes underway in the FDA under a new administration. The outstanding speakers provided insight on current topics, management issues and challenges at FDA, and on how the Agency was dealing with problems.

On January 30, 2009, the guest speaker, Dr. Stephen Sundlof, Director CFSAN. His presentation dealt with the contaminated 'peanut butter' outbreak that FDA addressed using a newly developed emergency "Incident Command System".



On March 5, 2009, Mr. Gary Buehler, Director of the Office of Generic Drugs (OGD), CDER gave insight into OGD's increasing workloads and the Office's work on Citizens Petitions since the Food and Drug Administration Amendments Act (FDAAA) was signed into law in 2007. Generic industry leaders expect that by 2012, 80% of prescriptions will be filled by generics.

On May 27, 2009, Dr. Joshua Sharfstein, Deputy Commissioner of the Food and Drug Administration, talked about the importance of communication, collaboration, transparency, and sound science and urged FDAAA membership to be actively engaged as "wise advisors" to FDA leadership.



On July 28, 2009, Rear Admiral Boris Lushniak, FDA Assistant Commissioner for Counterterrorism, described the focus and activities of the Office of Counterterrorism and Emerging Threats, including purchasing countermeasures (e.g., drugs, vaccines, etc.) under an emergency use authorization.

On October 21, 2009, Ms. Afa Asamoah, Special Assistant to the Principal Deputy Commissioner, described FDA's major transparency initiative. She explained that the initiative was a result of President Obama's desire for transparency and openness in government.



On January 21, 2010, Lawrence R. Deyton, M.S.P.H., M.D., the Director of FDA's new Center for Tobacco Products described the new organization and its mission, as well as its regulatory responsibilities relating to the content, marketing and sale of tobacco products mandated by the Family Smoking Prevention and Tobacco Control Act that was signed in June, 2009.

On February 4, 2010, Jeffrey E. Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, noted that CDRH set strategic priorities that call for implementation of a product life cycle approach, enhanced communication and transparency, a strengthened workforce and facilitation of innovation.



On March 15, 2010, FDAAA held a "Spring Celebration" luncheon at FDA's White Oak Campus in recognition of Dr. Margaret Hamburg's first anniversary as Commissioner of the Food and Drug Administration. Over one hundred FDA alumni and current Agency top management staff attended. FDAAA President, Alan Andersen, introduced Dr. Hamburg and gave some background on the well-established working relationship between the FDA Alumni Association and the agency. He listed recent presentations we've had from FDA leadership, efforts of the FDAAA to support CFSAN in responding to invitations from foreign governments on food safety and noted the recently established FDAAA International Network. Commissioner Hamburg said she was grateful for the partnership with FDAAA. She outlined goals to enhance the visibility and credibility of FDA, to strengthen the foundation needed to recruit and retain the best scientists and to respond to globalization.

Celebrated with Colleagues at the FDAAA Annual Dinner

On November 6, 2009, FDA Alumni Association members enjoyed their annual dinner at the Lakewood Country Club. President Alan Andersen conveyed the good news that membership reached 850. He recognized Associate Member Liaisons Fredda Valenti and Jim Simpson and he thanked Co-Chairs of the Activities Committee, Anne Marie Finley and Nancy Myers for arranging the pleasant evening that was highlighted by a presentation by the Acting Associate Commissioner for Regulatory Affairs, Michael Chappell.

Mike joined FDA in 1972 as a Consumer Safety Officer in Nashville, TN, moved to the level of Deputy Associate Commissioner for Field Operations in 2007 and was appointed Acting ACRA. He presented a lively talk covering recent changes at FDA and the need for FDAAA assistance in areas such as guidance and assistance for foreign regulatory authorities. Recent changes to the National Defense Authorization Act provide for rehiring of retirees on a part-time basis for mission critical positions, including training of employees, without reduction in their annuities.



Michael Chappell

Held Annual Meeting in Conjunction with FDLI Meeting

After welcoming members to the annual meeting held at the L'Enfant Plaza Hotel on April 22, 2009, outgoing FDAAA President Tony Celeste thanked everyone for the honor of serving the organization. Tony said that the strong leadership from Liz and Alan along with the other officers, the Board of Directors and Committees guarantees that members will continue to step up and maintain our mission.



Liz Krell, Tony Celeste, Robert Sauer, Alan Andersen

The FDAAA Treasurer, Alan Andersen, reported that the balance on January 1, 2009 was \$29,455.63.

Secretary Jeff Springer announced results of the elections for the new Board Members and the names of the new officers elected by the Board of Directors.

Activities Committee Co-Chair Nancy Myers introduced Co-Chair Anne Marie Finley and proceeded to highlight certain accomplishments during the last year. She cited the FDAAA lunches and the annual dinner which many recalled with pleasure. Nancy noted that Committee members met with FDA to offer FDAAA services for the “Torti fellowship program” and FDAAA expects to assist in training new FDA employees. In further efforts to be of service to FDA, the Activities Committee recently established a Subcommittee to provide an International Outreach Network chaired by Dr. Florence Houn.

A progress report from the Communications Committee Chair Edward Steele highlighted plans for improving the FDAAA website and included a presentation of the 2008 Annual Report by Lois Beaver.

Furthered FDAAA’s Mission by Working on Committees

The Executive Committee is chaired by the Chairman of the Board, Elizabeth D. Krell, Ph.D. and consists of the Association Officers. The Executive Committee supervises the business, property and affairs of the association. Committees are established by the Board of Directors to provide advice on matters of interest to the Association.

The Activities Committee co-chaired by Nancy Myers and Anne Marie Finley organizes gatherings such as luncheons with key FDA leaders and the annual dinner, and supports the FDAAA outreach mission to the FDA and regulators abroad. To further this goal, the Committee formed the FDAAA International Network, co-chaired by Florence Houn and Zili Li, that provides consultation with foreign regulatory authorities on the establishment and operation of regulatory programs. The committee also arranged two sessions where former senior-level Agency managers shared insights from their careers with FDA Commissioners Fellows.

The Communications Committee Chaired by Edward Steele maintains the Association website, coordinates the preparation of periodic email “Updates” to FDAAA members, prepares the Annual Report and promotes communication among all members of the Association. The Committee formed a Field Subcommittee to bring the Field into closer involvement in Association activities.

The Member Services Committee promotes the recruitment of current employees and alumni of FDA in the Association, maintains the Membership Directory and answers member questions is in need of a Chairman.

The Nominating Committee chaired by Daniel Michels is responsible for recommending members to the Board of Directors for each office of the Association to be filled by election of the members of the Association.

The Awards Committee, chaired by Carrie Cannady manages the FDAAA awards program which includes annual and ad hoc honors to members whose volunteer efforts help to grow FDAAA’s membership, ensure effective governance, provide meaningful member benefits and enhance the Association’s public standing. It serves as a primary conduit through which nominations for FDA’s Distinguished Alumni Award are solicited and considered.

Recognized the Outstanding Contributions of Members

Under the FDAAA Awards Program, members whose volunteer efforts assist the Association in fulfilling its mission in an outstanding manner receive recognition. We are proud to recognize the achievements of the following 2009 FDAAA and FDA Alumni Award Recipients:

FDA Distinguished Alumni Award

Former FDA employees who left the agency at least five (5) years ago, have a continuing and major impact on FDA as a whole, reflect FDA's values and exemplify an outstanding commitment to meeting the agency's mission of protecting the public health are eligible.

2009 FDA Distinguished Alumni Award Recipients:

Robert L. Lake - For distinguished service in improving the safety of the world's food supply and for exemplifying the spirit of service represented by FDA Alumni

Daniel L. Michels - For an exceptional life dedicated to protection of the public health and exemplary leadership that has enabled the FDA to fulfill its consumer protection mission.



Robert Lake and Daniel Michels

The Harvey W. Wiley Lecture

This lecture is named in honor of Dr. Harvey W. Wiley, the renowned physician-chemist who, at the turn of the 20th century, championed a legislative crusade against food adulteration, earning him the title of "Father of the Pure Food and Drugs Act" when it was enacted into law in 1906.

Lecturers shall be prominent figures from the fields of public health, health research, public health education, health care delivery, science journalism, food and drug law, and public policy-making, who can promote broader public enlightenment of, and support for, the mission of FDA; provide intellectually stimulating, futurist perspectives on 21st century roles of the FDA in public health and initiate a meaningful dialogue on innovative ways the FDAAA and its membership can impact the current and future mission of the FDA and its capacities to protect and promote the public health.

2009 Harvey W. Wiley Lecturers:



*Senator Orrin G. Hatch
United State Senator, Utah*



*Representative Henry A. Waxman
California's 30th Congressional District*

FDAAA Volunteer of the Year Award

Members of the FDAAA in good standing who make extraordinary contributions to the growth, viability and image of the FDAAA or to an affiliated chapter over a sustained period of time or demonstrate highly accomplished leadership in the development and conduct of Association programs or represent the Association in one or more extramural activities in a manner that positively reflects the ideals of the organization and substantially benefits the FDA or public health in general are eligible.

2009 FDAAA Volunteer of the Year Recipient



Wayne Pines

FDAAA Service Recognition Award

Persons who serve in leadership positions of the Association (e.g., Officer, member of the Board of Directors, Committee Chair) and whose service has a demonstrably positive effect on the growth, operational success and/or public image of the organization are eligible.

2009 FDAAA Service Recognition Recipients:



Tony Celeste



Ballard Graham



Jerry Halperin



Jeff Springer

Officers

Chairman, Board of Directors – Elizabeth D. Krell, Ph.D.

Vice Chairman – Robert W. Sauer

President – F. Alan Andersen, Ph.D.

Vice-President – Steven Niedelman

Secretary – Robert Eccleston

Treasurer – Florence Houn

General Counsel – Erika Lietzan, Esq.

Board of Directors

Elizabeth D. Krell, Ph.D.

Robert W. Sauer

Joseph R. Baca

James S. Benson

Andrew Bonanno

Joseph Levitt

Burton I. Love

Nancy Myers

Wayne L. Pines

Gail H. Sherman

John C. Villforth

Voyce Whitley

Committee Chairs

Activities Committee - Nancy Myers and Anne Marie Finley

Communications Committee - Edward Steele

Member Services Committee - Vacant

Nominating Committee - Daniel L. Michels

Awards Committee – Carrie Cannady

Associate Member Liaisons

Kimberly Holden

Fredda Shere-Valenti

CDR James Simpson



Serving Those Who Have Served