

Food and Drug Administration Alumni Association

Serving Those Who Have Served™

The Annual Report
9th Edition



2010 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:

- Abbott Laboratories (www.abbott.com)
- 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 (www.personalcarecouncil.org)

We especially thank Carla Moure for her assistance in preparing the 2011 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).

This Annual Report covers the period from the April 2010 Annual Meeting to the April 2011 Annual Meeting.

Message from the Chairman

This year the FDAAA celebrates its 10th year of existence and continues to thrive. While I've been actively involved for all of those years, the past 12 months as Chairman of the Board has given me an even greater appreciation for the dedication of our members to the success of the organization. All of your Board Members, Officers, Committee Chairpersons and Committee Members, and Associate Member Liaisons give tirelessly of their time and expertise to help meet the needs of our FDAAA members and to support the public health and regulatory mission of the Agency.



Robert W. Sauer
Chair

As you read through the accomplishments of your Association take pride in them and in any role you may have played. The list includes our strong staple programs such as our newsletter, our speaker luncheons with senior FDA leadership, and our annual dinners. We continue to meet future regulatory needs through our scholarship effort at Temple University, and we continue to work with the Agency including the nomination of candidates for the FDA Distinguished Alumni Award each year.

On the list you will also find new and challenging activities underway with our International Network and our new initiative - a "Spring Fling" Luncheon with FDA Commissioner Hamburg who has been very generous with her time and that of her senior staff for this event. We have also spent a good deal of time putting the financial health of the Association in good order by implementing improved financial planning and fiscal accountability; and this year we are introducing a new award "The Founders Award".

All of these activities take time and energy to plan and implement. The Board of Directors is supported by several very active committees: Awards, Finance, Communications, Nominating, Scholarship, and Member Services. I encourage all members and associate members to become knowledgeable about the work of these committees.

The FDAAA is, as you know, an all-volunteer organization. We survive and grow because of the time, effort, and commitment of so many people with one very important common characteristic, they have had the professional pleasure of being an employee of the best agency in government.

We believe that there is something that FDAAA is doing that could use your capable assistance. Help make FDAAA even better by finding a way to become personally involved this year. We can sure use the help, and you will be amazed at the satisfaction you will find by your participation. I look forward to our collective efforts making our 10th year our best ever.

Report from the President



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

As the chief operating officer of the organization, I'd like to give you a sense of what last year was like from an operational standpoint. 2010 was a year of significant change for the FDAAA, not all of it visible.

Look at what's new:

Efforts to develop our international network, for example, were realized with conferences in Asia and Africa, each with the FDAAA imprimatur and speakers drawn from our membership.

The first ever spring event featuring the FDA Commissioner and most of her senior staff.

The largest number of FDA speakers at FDAAA luncheon's, ever.

All of these things and more were highly visible.

Not so visible, and possibly linked to our mobile society, or maybe just related to individuals who tire of their ISP's service, is that we continue to lose touch with a portion of our membership each year. Given that we are volunteer run, finding the volunteer resources to keep up with all that has been difficult.

With so many members taking advantage of multiple year and lifetime memberships, we have reached the point where we need to use accrual accounting. That has had the good result that our budgets will be grounded in available resources. The bad result is that a "lost" member is difficult to contact for membership renewal and the dues income that comes with it!

We continue to examine new ways in which we can engage FDA alumni. For example, a couple of members have noted their interest primarily in the periodic updates that go out and not in the member pricing for luncheons, etc. --- because these individuals just aren't in the Washington, DC area. Might there be a membership structure just for them? We want to do what the membership wants to do, so feel free to offer any and all suggestions. This is your FDA Alumni Association and we would like it to be as responsive to your needs as possible.

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

Disseminated Information to its Members

Through informative FDAAA Updates, President Alan Andersen ensures that FDAAA members are aware of Association activities, events, new members and generally what is happening. This year, three dozen information-packed "Updates" were distributed to members by email.



See archived Updates posted on the FDAAA website http://www.fdaaa.org/publications_reports/FDAAA_Update_Archive.php.

Under the direction of Edward A. Steele, Chair of the Communications Committee, the FDAAA website is maintained to keep members current with FDAAA news and activities.



*Edward Steele
Chairman Communications Committee*

www.fdaaa.org



The members of the Communications Committee consists of Carla Moure, Lois Beaver, Joe Baca, Alan Andersen and Darryl Brown. Darryl Brown chairs a Field Subcommittee currently comprised of Section Representatives, Diana Kolaitis and Elaine Messa. This sub-committee was formed to stimulate involvement and to increase communication with FDAAA Alumni and Associate Members outside the Washington DC area.

Continued Support for the FDAAA Scholarship Fund

In April of 2006 the FDAAA established an FDAAA Centennial Scholarship Program at Temple University's School of Pharmacy. These Scholarships are awarded to deserving students in the Master's Degree Program in Quality Assurance and Regulatory Affairs. In the fall of 2010 the 8th and 9th Scholarship awards were made to the following deserving candidates:

Poonam Rajput



Poonam Rajput has industry experience in pharmaceutical and clinical research. She has worked as a Clinical Research Associate in various therapeutic areas (Oncology, Diabetes, and Cardiovascular) with PPD and iGATE Clinical Research International. Prior to this, Poonam worked as a Marketing Executive for USV Ltd., GlaxoSmithKline. She handled their Mumbai territory in India, achieving the Best Performance award at USV. With a BS in Pharmacy and a post-graduate Diploma in Clinical Research from India, Poonam is currently pursuing her MS degree in Quality Assurance and Regulatory Affairs from Temple University.

Paul Mouris



As an Investigator with the Food and Drug Administration in White Plains, NY, for the past six years, Paul inspects pharmaceutical manufacturers to ensure that they are manufacturing safe and effective products in accordance with Current Good Manufacturing Practices. He is committed to staying on the cutting edge of technology and pharmaceutical development.

The FDAAA contributed an additional \$1,025 to the Centennial Scholarship fund in 2010. Since the fund was established, FDAAA has contributed a total of \$52,297.

Temple University President Ann Weaver Hart thanked FDAAA for its latest gift in a June 4 letter. "I would like to offer my sincere thanks for the Food and Drug Administration Alumni Association's recent gift," Weaver wrote. "I am excited to be a part of a community where philanthropy helps to strengthen the university and support its continued growth.

"The generous support of alumni and friends has greatly influenced the shape of Temple University, particularly in recent years," she added. "Our facilities continue to expand, faculty recruitment is at an all time high, and our growing student population created a thriving community on our campuses. All of these improvements clearly illustrate the transformative power of giving."

The FDAAA scholarship is open to current and new students in Temple's QA/RA graduate program who are not eligible for tuition reimbursement at their organization. The scholarship is awarded on the basis of financial need and academic merit. The award consists of the tuition costs for one QA/RA course (exclusive of computer and technology and other applicable fees). A selection committee consisting of the dean, assistant dean, director of graduate studies, and at least two QA/RA faculty members make the final selection.



School of Pharmacy

TEMPLE UNIVERSITY®

For further information, contact:

Temple University School of Pharmacy
Quality Assurance/Regulatory Affairs
Graduate Program
Attention: Wendy Lebing, MALD, MS,
Assistant Dean
Phone: 267-468-8560
Fax: 267-468-8565
Web: www.temple.edu/pharmacy_QARA
E-mail: qara@temple.edu

An FDAAA Centennial Scholarship Application Form is available at www.temple.edu/pharmacy_QARA/FDAAAAScholarship_apply.pdf.

To make a donation to the scholarship fund or for more information, contact:

F. Alan Andersen, Ph.D.
FDAAA President
1101 17th St., NW, Suite 412
Washington, DC 20036
Phone: 202-331-0651
andersena@cir-safety.org

Checks should be made out to the FDAAA Centennial Scholarship Fund. All donations are tax deductible, as permitted by federal law. (FDAAA is a 501(c)(3) non-profit organization.)



Held FDAAA Board of Directors Meetings

The Board of Directors met on July 24, 2010, November 12, 2010 and January 24, 2011, in addition to the Annual Meeting on April 22, 2010. At the April meeting, new Directors were introduced, and the resignation of Bob Eccleston as Secretary of the Association was announced.

At the July meeting, Gail Sherman was introduced as the new Secretary and Suzanne Sensabaugh as the Chair, Member Services Committee. To further enhance the work of the Association, all Board members were asked to join at least one Committee. An ad hoc Committee was approved to review financial issues and make recommendations to the Board.



Gail Sherman



Suzanne Sensabaugh



In November, Scott Danzis was introduced as the new Counsel for the Association, and at the January meeting, was approved by the Board. Dr. Andersen thanked Erika Lietzan for her service as Counsel to the Association. The Member Services Committee proposed an annual dues solicitation process.

In January the Board approved a new budget process and proposal to establish a Finance Committee to review and recommend on annual budgets of the Committees and Board. At this meeting the Board also approved a new Founders Award to recognize Board members and Committee Chairs who have served with distinction in a leadership capacity.



The Executive Committee has established a process for monthly teleconferences with Committee Chairs to review Committee activities and set agendas for future meetings.

The Board agreed to continue the Scholarship to Temple University and has begun an active donation solicitation process to fund this scholarship.

At the conclusion of the meeting special recognition was given to the Board Members who help establish the Association that are circulating off the Board.

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 four additional luncheons during the twelve months covered by this report. They featured 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.

The May 27 luncheon featured remarks from Michael Taylor, Deputy Commissioner for Foods. Mr. Taylor discussed the challenges that food safety presents and what is being done to cope with the enormity of these issues. He discussed the pending legislation that would give FDA more authority to regulate foods and would place increased responsibilities on the industry to maintain preventative controls.



The Association welcomed Dr. Karen Midthun, Director, Center for Biologics Evaluation and Research to the luncheon on November 18. Dr. Midthun provided a CBER update. She mentioned their public health focus and work in emerging infectious diseases such as pandemic influenza as well efforts to combat bioterrorism

Those who gathered for the December 8 luncheon were well instructed by Dr. Gerald Dal Pan, Director, Office of Surveillance and Epidemiology (OSE) in CDER.. OSE has the lead in such issues as new proprietary claims, look alikes, sound alikes, and more. An additional responsibility tied to safety evaluation being carried out by OSE is the Sentinel Initiative. This agency-wide initiative will evaluate data from initially 25 million patient records in 2010 to 100 million in the year 2012. Much of the development of the program is being carried out through a contract with Harvard University.



On February 25, FDAAA attended the luncheon, to hear Jay Epstein, Director of CBER's Office of Blood Research and Review, discuss the current challenges in keeping the blood supply safe. Dr. Epstein has been director of OBRR since 1993.

FDAAA Honors Commissioner Hamburg at the 2nd Annual “Spring Fling” Luncheon



FDA Commissioner Dr. Margret Hamburg was honored at this year’s “Spring Fling” luncheon in the Great Room on the FDA White Oak Campus on March 30, 2010. This is the second year of what is expected to be an annual event where the Food and Drug Administration Alumni Association (FDAAA) and FDA top management join together in a picnic lunch.



This year over one hundred current and former Agency personnel had the opportunity to chat about old times, enjoy a tasty barbecue lunch and hear the Commissioner speak of the accomplishments and challenges facing today’s FDA. Despite the colorful daffodils and high spirits of the attendees, it wasn’t exactly a typical Washington spring day. However, the cool weather didn’t dampen the good time that was had by all.

In FDAAA President Alan Andersen’s introductory remarks, he thanked Nancy Myers and Ann Marie Finley for arranging the event and Commander James Simpson for coordinating the shuttle service and the escorting of members through security. He took a moment to acknowledge the passing of Emil Corwin at age 107. Emil retired from FDA at age 96 as the oldest federally employed public affairs officer. He died of cardiac arrest on March 15th.

He thanked the Commissioner for taking time to spend with the Association and made reference to a recent letter of endorsement the Commissioner sent to FDAAA in which she said,

“As we approach the planning cycle for the next FDA/FDAAA spring event, I feel compelled to let you know how impressed I have been with your Association. At every point in my leadership I come to recognize the importance of the historical backbone that your colleagues offer to FDA, and I am grateful for the perspective that you and others offer. I believe that it is especially useful to continue dialogue among us. The periodic luncheons FDAAA sponsors are an example of educational interchanges that benefit both our organizations.

Please add my strong endorsement of FDAAA to that of my predecessors. It is clear to me that we may have embarked on a perfect partnership.”

On behalf of the Association, Andersen said “We appreciate your endorsement and we will continue to support the mission of the Agency.”

Commissioner Hamburg then welcomed the Association back and praised the FDAAA for carrying the FDA banner and serving as ambassadors for the Agency. She reflected on the fact that we are working in a complex world in complex times. That the globalization of the products the Agency regulates has changed the way we must do business and while it presents many new challenges it is also very exciting times. FDA finds itself in the center of it all.

She was thankful for the growing appreciation for FDA and increased external support the Agency is receiving. This not only included the Congressional support but from organization such as the FDAAA and the Alliance for a Stronger FDA. While she acknowledged that we are in hard times, particular as there are looming threats of a possible government shut down, she displayed a tremendous sense of excitement about the accomplishments made during the past year and the plans for the future. She repeatedly made reference to what an extraordinary organization FDA is and how proud she is of the staff and its recent accomplishments.

She particular identified the good work that Dr. Lawrence Dayton and the Tobacco Center has done to meet the Congressional mandates for implementing the Family Smoking Prevention and Tobacco Control Act on schedule; the leadership role that Mike Taylor, Deputy Commissioner for Foods is playing to implement the Food Safety Modernization Act; the way in which Dr. Karen Midthun, Director, Center for Biologics handled the H1N1 pandemic of last year and the tremendous job that Dr. Jeffrey Shuren is doing to make in improvements in how medical devices are regulated.

She then provided an update on the continuing build out of the physical facilities at the White Oak Campus. She seemed particularly excited about the plans for commercial growth in the area surrounding the campus. This includes plans to build a hospital complex, a life science research park and commercial services such as hotels, business offices, restaurants and shops. All this will make working at White Oat more attractive to FDA employees.

Dr. Hamburg closed, by thanking the Association for it dedication to the mission of the Agency. She extended her best wishes to the FDAAA for continues success and expressed her hope that we can meet again next year for the 3rd Annual “Spring Fling.”



Celebrated with Colleagues at the 2010 FDAAA Annual Dinner



Thanks to Board Member James Benson who again arranged this event held at the Lakewood Country Club in Rockville, MD on October 2, 2010.

FDAAA members and guests enjoyed an evening with former FDA colleagues and friends. This annual event allows those in attendance to catch up on old times over wine and beer and a variety of hors d'oeuvres, followed by a delightful sit-down dinner. This year's dinner speaker was Ellen Morrison, Director of the Office of Crisis Management. The Activities Committee Co-Chair, Nancy Myers organized the event and introduced the dinner speaker.

Ellen informed the group about advances FDA has made in tracking emergency situations in its state-of-the-art Emergency Operations Center on the White Oak Campus. Her presentation showed the physical command center and the sophisticated software FDA now has available to help coordinate federal-state responses to food contamination outbreaks, natural disasters and other crisis situations. She focused on how the Agency was able to respond to the Gulf Oil Spill in a coordinated way with Centers for Disease Control and Prevention and the involved State agencies. A copy of her slide presentation is attached.



The annual dinner provided another opportunity for current and former FDA employees to get together on a social basis and to learn of the latest advances at the Agency. – A good time was had by all.



Increased Consultation with Foreign Regulatory Authorities



Florence Houn and Zili Li

Since February 2009, FDAAA's Activities Committee subcommittee, the FDAAA International Network (FDAAAIN), has been acting as a clearinghouse for requests for FDA alumni assistance by foreign health authorities and 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. In 2010, the FDAAAIN received approximately 10 requests from foreign governments, the US FDA, and other international agencies, such as the WHO, to solicit the FDA alumni membership for expertise to assist regulatory educational efforts. In addition, the FDAAA co-sponsored regulatory science educational seminars at China DIA, with the Chinese State Food and Drug Administration in Beijing, at US DIA in Washington, DC, with the Korean Food and Drug Administration, and in conjunction with the Asia Pacific Economic Cooperation (APEC) Chinese Taipei Taiwan Food and Drug Administration. FDAAAIN is a reference for APEC and sits on the training subcommittee. FDAAAIN is also engaging in activities to promote regulatory scientific education and outreach in Africa and in the area of food safety.



November 3, 2010 FDAAAIN gives lecture at APEC Good Review Practices Training in Chinese Taipei



August 9-11, 2010 The Korean Food and Drug Administration and FDAAA co-sponsor an educational seminar in Seoul, Korea.

Recognized the Outstanding Contributions of Members

The FDAAA Awards program continues to honor its active members with a variety of awards. In addition we work closely with FDA to recognize the efforts of former FDA employees who have continued to support the agency's mission well beyond their retirement. The awards program is administered through the FDAAA Awards Committee, chaired by Carrie Cannady

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.

2010 FDA Distinguished Alumni Award Recipients:



Joe Levitt



Bill Hubbard

Joe Levitt - For exceptional leadership and advocacy of FDA through education and information thereby promoting greater understanding and support of the agency's mission to protect the public health. (recipient nominated by FDAAA)

Bill Hubbard - For unparalleled commitment to and tireless efforts in support of the Food and Drug Administration's mission of promoting and protecting the public health of our nation. (recipient nominated by FDAAA)

John Finlayson, Ph.D. - For 51 years of distinguished service to the cause of public health, through research, regulation, and inspired mentoring of the current generation of CBER scientist-regulators.

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.

The 2010 Harvey W. Wiley Lecture:



*Law Professor Emeritus
Richard Merrill*

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