

Food and Drug Administration Alumni Association

Serving Those Who Have Served

2008 Achievement Highlights



The Annual Report
7th Edition

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.fdpi.org)
- Kendle International, Inc. (www.kendle.com)
- 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 2008 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 the information as presented is incorrect. Readers are encouraged to report incomplete, inaccurate, or new information to Ed Steele (esteele@easconsultinggroup.com).

Report from the Chairman



It is satisfying to review the activities and services provided last year due to the dedication and efforts of so many members of the FDA Alumni Association. This report highlights accomplishments for which I wish to express deep appreciation to each individual who selflessly contributed to the fulfillment of FDA's mission. My gratitude is extended to the members of the Board of Directors, to the Officers, to the Committees that produced valuable and tangible results, and to others who worked to help achieve our goals or provided other support.

In view of the level of enthusiasm and plans for future activities, FDA's mission will continue to thrive and serve the needs of its members and the FDA.

FDA's Mission

The Food and Drug Administration Alumni Association, Inc. is a non-profit volunteer service organization that:

- promotes the public health mission of the FDA by providing the assistance of alumni experts with specialized technical, scientific, and institutional knowledge;
- provides educational and professional development opportunities to enable FDA alumni to stay abreast of current, challenging issues facing the agency;
- assists FDA in its ongoing capacity-building efforts by making students and professionals aware of public service opportunities at the agency;
- educates the public about the ever-expanding mission of the FDA and the importance of its work;
- sponsors outreach programs to educate and guide health authorities throughout the world in their efforts to establish and improve national regulatory systems relating to food, drugs, biologics, medical devices, and other health care and consumer products; and
- honors exceptional contributions to FDA's public health mission by former FDA employees and other individuals.

Remarks from the President



It has been my distinct honor to serve as the President of our Association for the last three years. This is my last message as President. I feel that I am leaving at a time when we have established strong leadership throughout the organization. Our board, the incoming officers and our committees are constituted with dedicated members that will direct and support our Association for the upcoming year. It is with pleasure that I look back on working with FDAAA colleagues over the last year. My gratitude extends to all of you who contributed to the realization of the fundamental goals in our mission statement through your guidance, leadership, work on committees and other services. Together we accomplished a lot that provides a degree of satisfaction and suggests a way forward in continuing the initiative. New ideas, new members and the enthusiasm of dedicated individuals will carry us forward. I suggest that while you enjoy this report on the FDAAA year in review, you reflect on ways we can better serve our membership and the FDA. Here is a look at some of last year's achievements:

- Communicated with Membership Through More Than 30 Email Updates
- Continued Support of the FDAAA Centennial Scholarship Program
- Held Luncheons to Learn What's Happening at FDA
- Held Annual Meeting in Conjunction with FDLI and FDA Annual Meeting
- Sponsored Commemoration of the 50th Anniversary of the Signing of the Food Additives Amendment to the FD&C Act
- Held FDAAA Board of Directors Meeting
- Celebrated with Colleagues at the FDAAA Annual Dinner
- Furthered FDAAA's Mission by Working on Committees
- Recognized the Outstanding Contributions of Members

I also welcome the 66 new members that joined our Association this year. It is gratifying to see how the FDAAA has grown from what was an idea of a few to a thriving organization with a membership of 782 members in less than a decade.

The Year in Review — Highlights of FDAAA's Achievements

★ Communicated with Membership Through More Than 30 Email Updates

Everyone knows Alan Andersen through his helpful and informative emails. He keeps FDAAA'ers informed about activities, events, and what is happening with new and old members. Alan also facilitates the distribution of requests for assistance and professional opportunities. During 2008 there were dozens of requests for assistance from FDAAA to provide training and regulatory advice on various FDA matters including food and drug import regulations, food safety issues, bioterrorism, pharmaceutical science, labeling, sampling and inspection. Requests came from domestic sources such as FDA, JIFSAN, USDA, George Washington University School of Public Health and often involved training and assistance to foreign regulatory authorities in Asia, South America, Africa, and the Far East. The Association is also working with FDA to assist in training fellows under a recently established two year program. In view of the numerous topics covered and the valuable information provided, Alan's "Updates" are essential for the smooth functioning of the Association.

★ Continued Support of the FDAAA Centennial Scholarship Program



In 2006, FDAAA established an endowment to commemorate the 100th anniversary of the Pure Food and Drugs Act and to encourage academic training in regulatory and quality issues. The endowment fund is currently over \$52,000. Temple University was selected for the FDAAA Centennial Scholarship based on its outstanding pharmaceutical quality assurance and regulatory affairs training and longstanding relationship with the FDA.

The 2008 FDAAA Centennial Scholarship Awardee is Khyati Dave, a student and research assistant at Temple's School of Pharmacy. When she learned about Temple's renowned QA/RA program, Khyati Dave left India where she worked as a QA analyst to pursue a

master's degree in the pharmaceutical sciences with an interest in US and global regulations. Her dream is to return to the industry after graduation to pursue a career in drug discovery. Khyati said, "I cannot adequately express my thanks to the FDAAA for helping me to advance my passion for drug discovery. I am thrilled to receive the scholarship, which has motivated me to work even harder at my research and courses."

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

"To be effective, we need the help of organizations like yours, so I encourage you to keep informed, stay engaged, and continue to serve as a great national resource! I wish you continued success in the year ahead. As a Philadelphia native, I also congratulate your Association for its ongoing work with the Temple University School of Pharmacy to sponsor a scholarship program to aid academically deserving students enrolled in graduate studies in quality assurance and regulatory affairs. Keep up the great work!"

Andrew von Eschenbach, Commissioner FDA

★ Held Luncheons to Learn What's Happening at FDA

Wayne Pines, Anne Marie Finley, Nancy Myers, and the members of the Activities Committee organized the 2008 FDAAA lunches, complete with superb luncheon speakers. These speakers, consisting of a veritable “who’s who” in FDA, briefed us on current “hot button” topics, on management issues and challenges at FDA, and on emerging problems faced by the Agency. Luncheons were held near the Parklawn Building at the Far East Restaurant in Rockville, MD.



- The January 11 luncheon featured Jesse Goodman, M.D., MPH, Director, Center for Biologic Evaluation and Research, who informed participants about the latest developments in the area of vaccines and biological products.
- On February 2, Timothy Cote, Director, Office of Orphan Products Development, Office of the Commissioner, gave FDAAA luncheon attendees an overview of “25 Years of the Orphan Drug Act”.
- Those who attended the June 12 luncheon were given insight into the changes in store for FDA when Jane Axelrad, Office of Regulatory Policy, Center for Drug Evaluation and Research, provided insight on the “FDA Amendment Act”.
- At the September 25 luncheon, Dr. Daniel G. Shultz, Director of the Center for Devices and Radiological Health, discussed the Center’s 2009 priorities and initiatives.

★ Held Annual Meeting in Conjunction with FDLI and FDA Annual Meeting

Highlights of the March 26, 2008 FDA Alumni Association Annual Meeting held at the L'Enfant Plaza Hotel, Washington, DC, included the election by the eligible members of James Benson, Joseph Levitt, Gail Sherman, John Villforth, and Voyce Whitley to the Board of Directors (three year terms). The Board of Directors elected the following as Officers of the Association (one year term): Chair - Elizabeth Krell, Vice-Chair - Robert Sauer, President - Anthony Celeste, Secretary - Jeffrey Springer, Treasurer - Alan Andersen, and General Counsel - Erika Lietzan. Associate members selected Lois Beaver, Kim Holden and Fredda Shere-Valenti as FDAAA Liaison Members. Following reports from the Committees, with emphasis on the activities, there was a lively discussion on how to distinguish between the FDAAA (the “real” thing) and the FDA Amendments Act (that is FD triple A).

For the first time, the Harvey Wiley Award was presented during the FDLI plenary session to which FDAAA members were invited. The 2008 recipient of the Harvey Wiley Award was John C. Villforth. John reminded the audience of the divergence of opinion between an FDLI founding father, Mr. Dunn, who supported the educational approach and Harvey Wiley who preferred a “cop on the beat” approach. Agreement between FDA and FDLI became apparent when FDA commissioner Mac Schmidt brought it all together in a unifying statement: “FDA is an educational institution, we just put slow learners in jail!”

A state of the agency presentation by FDA Commissioner Andrew von Eschenbach emphasized the importance of science in making regulatory decisions. That perspective was reflected later in the meeting when the science board subcommittee reported on science at FDA. The presenters pointed out that the report was mainly an acknowledgment that FDA has been given too much to do with too few resources.

★ Sponsored Commemoration of the 50th Anniversary of the Signing of the Food Additives Amendment to the FD&C Act



FDAAA supported and contributed to the successful observance of the 50th Anniversary of the Food Additives Amendment (FAA) to the Federal Food, Drug, and Cosmetic Act. The celebration was held at the Wiley Auditorium, in the Center for Food Safety and Applied Nutrition (CFSAN), on September 15, 2008. FDAAA publicized the event, provided the refreshments, and displayed insightful historical artifacts to educate the attendees about the occasion.

Speakers at the anniversary event included Suzanne White Junod, FDA’s historian, Frederick Degnan, previously Associate Chief Counsel in FDA’s Office of the Chief Counsel and a food additive litigator, and former Director of CFSAN, Joseph Levitt, who made a presentation on behalf of the FDA Alumni Association. Other featured speakers included another former CFSAN Director, Sanford Miller, who discussed the “intersection of science and policy at FDA.” Former FDA Deputy Commissioner for Policy, Michael Taylor, explored what lies ahead for food additive regulation, while Jerome Heckman, from the law firm of Keller & Heckman, shared his thoughts on how the regulatory environment has unfolded over the past 50 years. Consumer advocate Michael Jacobson, executive director of the Center for Science in the Public Interest, looked at the food additive laws with “50 years of hindsight.” Early in his career, Jacobson wrote a book titled *Eater’s Digest: The Consumer’s Fact-Book of Food Additives*.

★ Held FDAA Board of Directors Meeting



On October 23, 2008, the Board met to assess the current situation of the association and to address challenges laid out by the Chair, Elizabeth Krell. Previous discussions from the June 17, 2008 meeting facilitated by Jake Barkdoll and Doug Sporn were reviewed. Based on a poll of the membership it was concluded that there is a strong interest in publicly supporting FDA, the email communications from Alan are great and the FDAA luncheons and dinners are a

local success. There was also significant support from the members for the Association to assist FDA wherever and whenever possible.

In the course of the October meeting, a status report on the Centennial Scholarship Fund was presented by Bob Sauer who was accompanied by Peter Doukas and Wendy Lebing from Temple University. Peter and Wendy announced that Temple had contributed \$15,000 to the scholarship fund as a result of funds obtained from a symposium co-sponsored by the university and FDA. Alan Andersen provided the Treasurer's Report and outlined the work of the Members Service Committee. The outcome of the work of the Nominating Committee was presented by Dan Michels and that of the Awards Committee by Bob Eccleston. Tony Celeste's presentations led to the establishment of a Vice-President position. Ed Steele was approved as Chair of the Communications Committee. Fredda Shere Valenti presented the Associate Members Liaison report prepared by herself along with Kimberly Holden and Lois Beaver. Elizabeth Krell and General Counsel Erika Lietzan discussed insurance for Directors and Officers. Joe Levitt and Alan Andersen described the successful outcome of the celebration of the 50th anniversary of the Food Additives Amendment. Wayne Pines, Nancy Myers, and Anne Marie Finley reported on the work of the Activities Committee including the FDAA luncheons and the Annual Dinner. Alan Andersen presented a proposal from the University of Richmond. On a sad note, John Villforth noted the death of honorary FDAA member, former Congressman Paul Rogers.

★ Celebrated with Colleagues at the FDAA Annual Dinner

Thanks to Board Member James Benson who arranged this event held on November 1, 2008.

More than 80 FDAA members and guests enjoyed an evening with former FDA colleagues and friends. There was wine and beer, a variety of hors d'oeuvres, and a delightful chicken/crab cake combo. The highlight of the evening was meeting Dr. Frank Torti, FDA's Principal Deputy Commissioner and Chief Scientist. In his prepared remarks, Dr. Torti emphasized the importance of sound science in building the effectiveness and credibility of the Agency as its regulatory responsibilities increase. Dr. Torti spoke of his vision that "Top quality regulatory science will improve regulatory decisions, regulatory consistency and speed the approval of new products." It should be noted that in January 2009, Dr. Torti became Acting Commissioner of FDA.



★ Furthered FDAAA's Mission by Working on Committees

Committees are established by the Board of Directors to provide advice on matters of interest to the Association.

The Activities Committee Co-Chaired by Wayne L. Pines, Nancy Myers, and Anne Marie Finley organizes gatherings and supports the FDAAA outreach mission to the FDA and regulators abroad. See the 2008 review on the luncheons with key FDA leaders and section on the annual dinner for a sample of the work of this Committee.

The Communications Committee Chaired by Edward Steele maintains the Association website, coordinates the preparation of periodic email "Updates" to FDAAA members, and prepares the Annual Report. The 2008 achievements of this Committee are evidenced on the new website and in this report.

The Finance Committee Chaired by Jerome A. Halperin provides advice to the Board on matters concerning the financial affairs of the Association.

The Member Services Committee Chaired by F. Alan Andersen, Ph.D. promotes the recruitment of current employees and alumni of FDA in the Association, maintains the Membership Directory, and answers member questions. During 2008, this Committee brought 66 new members on board.

The Nominating Committee Chaired by Daniel L. Michels is responsible for recommending members to the Board of Directors for each office of the Association to be filled by election of the member of the Association. The outcome of their 2008 recommendations is reflected in the section on FDAAA Leadership in this report.

The Awards Committee Chaired by Robert C. Eccleston manages the FDAAA awards program. See the section below on the FDAAA 2008 Awards to view the achievements of this Committee.

★ 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 2008 FDAAA and FDA Alumni Award Recipients:

FDA Distinguished Alumni Award:

Eligibility: Former FDA employees who left the agency at least five (5) years ago and meet the following criteria:

- 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.

2008 FDA Distinguished Alumni Award Recipients:



Elizabeth D. Krell, Ph.D.

For exceptional scientific leadership of FDA programs, international harmonization, consensus standards, device trade association programs, and alumni relations that contribute to the public health.



Arthur Norris

For vision, dedication and commitment to advancing FDA science, education and public health goals.



Linda A. Suydam, D.P.A.

For exceptional management of FDA programs in medical devices, radiological health, and agency-wide leadership to fight abuse and insure safe use of over-the-counter medicines.

Harvey W. Wiley Lecturer:

Eligibility: 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;
- 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.

2008 Harvey W. Wiley Award Recipient:



John C. Villforth, former CDRH/FDA Director and former President, Food and Drug Law Institute

Description: A lectureship 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. The Lecture is presented at the FDAAA Annual Meeting each April.

FDAAA Volunteer of the Year Award:

Eligibility: Members of good standing of the FDAAA 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.

2008 FDAAA Volunteer of the Year Award Recipient:



William Rados, Chairman of the FDAAA Communications Committee

FDAAA Service Recognition Award

Eligibility: 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.

2008 FDAAA Service Recognition Award Recipients:



Debra Lewis



Richard Merrill, Esq.

2008 FDAAA Certificate of Appreciation

Eligibility: Any individual who is an FDAAA member or non-member, or entity, who/that:

- makes a remarkable contribution, either on a one-time or continuing basis, to the operation or financial standing of the Association (e.g., pro bono services, large donation);
- provides highly-dependable, productive volunteer service to the FDAAA;
- serves in an appointed or elected position of responsibility in the FDAAA;
- is a guest speaker or participant at an FDAAA-sponsored event;
- performs a charitable act that exemplifies the goal and values of the FDAAA;
- offers a unique idea or recommendation that is adopted and enhances the efficiency, effectiveness and/or integrity of the FDAAA.

2008 FDAAA Certificate of Appreciation Recipient:



Fredda Shere-Valenti

The FDAAA is Growing

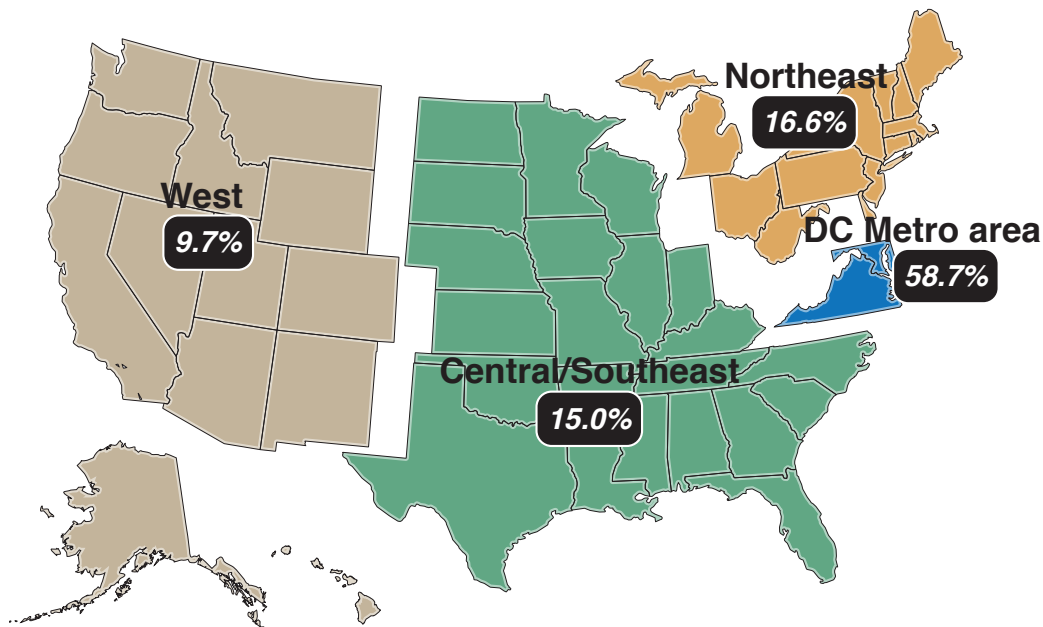
At the close of 2008, FDAAA had 782 members.

Alumni Members: 578

Associate Members: 185

Honorary Members, Distinguished Members, and Friends: 19

2008 Membership by Location: FDAAA members are located throughout the U.S., its territories, and in foreign countries.



Field	41.3%	U.S. Territory	3
		Commonwealth of Puerto Rico	3
West:	9.7 %		
Northeast:	16.6 %	Foreign Countries:	5
Central/Southeast	15.0 %	Italy	1
		People's Republic of China	1
DC Metro area	58.7%	Singapore	1
		Switzerland	1
		Thailand	1

We Welcome New Members

During 2008, 66 new members joined the Association. The new members are:

Charles Anello, ScD.	Joseph Hanig
Binita Ashar, MD, MBA	Donald B. Hare
Joseph R Baca.	Kimberly A. Holden
Virginia Beakes-Read, JD	Florence Houn, MD
Andy Bonanno	Janine W. Jarvela
Mary Elizabeth Brooks	Lawrence (Larry) R. Johnson
Katya Buck Kristen MD	Raj Kishore, PhD
D. Bruce Burlington, MD	Laura Kragie, MD
Ellen Chen	George W Kraus, Jr.
Robert F. Church	Cindy E. Lachin
James Lindsay Cobbs	Robert J. Landry
Jean M.Cooper, PhD	Frank Makison
Timothy R Cote, MD	Lisa M. Malandro, MBA
H. Gordon Cox	Robert A. Miranda
Ranie Ann Crompton	Michael Andrew Misocky, PhD
Marjorie F. Dannis MD	Craig Ostroff, Pharm.D.
Beatrice Droke	Ben F. Oswald
Tom DuT, MD, PhD	Thomas J. Ott
Bernadette Dunham, DVM, PhD	Glenn Rahmoeller
Keary Louis Dunn, Esq.	Theodore L. Rotto
Earl S.Dye, PhD	Frank Edward Scarbrough
Sandra Rae Erickson	Brenda C. Seidman
Robert A. Eshelman	Albert T Shelton, PhD
Marc M. Feinberg	Michelle Annette Smith, PhD
Jeffrey K. Francer	Larry Stringer
John Francis Glass	Roderick Taylor
Mark Jay Goldberger, MD	Cynthia A.Tillman
Karen L Goldenthal, MD	Hai Thi Truong
Jorge L. Gonzalez	Kwame O. Ulmer
Angus Grant	Sheila D. Walcoff, Esq.
Jennifer A. Grayson	Virlie Walker
Lawrence Jerome Grylack MD	LaKisha Monique Williams
Ravi Harapanhalli, PhD	Walter L Zielinski, PhD

Officers

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

Vice Chair – Robert W. Sauer

President – Anthony C. Celeste

Secretary – Jeffrey B. Springer

Treasurer – F. Alan Andersen, Ph.D.

General Counsel – Erika Lietzan

Board of Directors

F. Alan Andersen, Ph.D.

James S. Benson

Ballard H. Graham

Jerome A. Halperin

Elizabeth D. Krell, Ph.D.

Joseph Levitt

Burton I. Love

Wayne L. Pines

Robert W. Sauer

Gail H. Sherman

John C. Villforth

Voyce Whitley

Associate Member Liaisons

Lois Ann Beaver

Kimberly Holden

Fredda Shere-Valenti

Committee Chairs

Activities Committee - Wayne L. Pines, Nancy Myers, and Anne Marie Finley

Communications Committee - Edward Steele

Finance Committee - Jerome A. Halperin

Member Services Committee - F. Alan Andersen, Ph.D.

Nominating Committee - Daniel L. Michels

Awards Committee - Robert C. Eccleston