Food and Drug Administration Alumni Association

Serving Those Who Have Served ™

The Annual Report
11th Edition

2012 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 appreciated the support of the following organizations:

- Abbott Laboratories (www.abbott.com)
- Alston & Bird, LLP (www.alston.com)
- Catalyst Healthcare Consulting, Inc. (www.catalysthcc.com)
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- EAS Consulting Group, LLC (www/easconsultinggroup.com)
- Food and Drug Administration (www.fda.gov)
- Food and Drug Law Institute (www.fdli.org)
- Greenleaf Health, LLC (www.greenleafhealth.com)
- Hogan Lovells, LLP (www.hoganlovells.com)
- Temple University School of Pharmacy (www.temple.edu/pharmacy)
- Personal Care Products Council (www.personalcarecouncil.org)

We especially thank Paul Raynes for his assistance in preparing the 2012 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 2012 Annual Meeting to the April 2013 Annual Meeting.

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 the 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 the FDA and other informative sites
- Membership Directory

Message from the Chairman

Joe Levitt
Chairman

When I became Chairman of the FDA Alumni Association last year, I told the Board of Directors that our number one goal should be to raise the visibility of the organization. The idea was that, by raising our profile, we would build membership, be able to expand our activities, and sustain us into the future -- an approach reminiscent of the famous movie line: "If you build it, they will come!"

Little did I imagine that, within a matter of months, I would be standing on the podium at the FDA's 50th anniversary celebration of the 1962 Drug Efficacy Amendments -- itself one of the great milestones in agency history -- and receiving from FDA Commissioner Margaret (Peggy) Hamburg, on behalf of the FDA Alumni Association, the Frances O. Kelsey Award for Excellence and Courage in Protecting the Public Health. It was one of the few times in my life when I was, quite literally, rendered speechless.

But not for long! We soon hosted a holiday party to commemorate the award -- one of the best attended FDAAA events in recent years. We formed an ad hoc Board committee to identify ways to further strengthen our ties to the agency. And we created a new committee dedicated to reaching out to current and former FDA'ers so we can attract and retain new members. Looking ahead, we are exploring ways to hold an FDA alumni reunion sometime in 2014. There is just nothing quite like reconnecting with old friends.

The point is, that we all share a common bond -- a deep belief in the mission of the FDA and a dedication to, and friendship with, our many colleagues who work or have worked at this very special agency. The esprit de corps at FDA is unmatched by any other Federal agency, and that fellowship extends well into our retirement days.

As we look to the future, we also need to honor those who have taken us this far. Longtime FDAAA president, Alan Andersen, Ph.D., is stepping down so he can move out west. We all owe Alan an enormous debt of gratitude for his tireless efforts in championing FDAAA in all quarters. Luckily, with the modern internet, Alan can (and will) continue publishing our monthly newsletter from his retirement habitat in Nevada.

I also want to thank Ed Steele for agreeing to take up the reins as our incoming president, as well as our other officers, board members and committee chairs. These volunteers are truly the lifeblood of our organization.

So please join me in honoring the past, invigorating the present, and building an even better future!

Joe Levitt, Chairman

Report from the President

F. Alan Andersen, Ph.D.
President

There are several themes worth noting for the FDA Alumni Association annual report, from my perspective as President – globalization, localization, and --- money.

Like FDA, we are becoming increasingly global, and not just in terms of where our members choose to live/work but in terms of where we are doing our outreach. The FDAAA international network is alive and well under the leadership of Flo Houn and Zili Li, and continues to offer opportunities at educational events in Asia and elsewhere. The FDAAA logo and speakers drawn from our membership are appearing more and more globally.

More locally, we have begun to sponsor brown bag lunches on the White Oak campus. Such events are cheaper for our members and guests since we're not paying for restaurant food. This facilitates more FDA staff attendance. And, after all, FDA staff are "alumni-in-training." And getting through security at White Oak isn't as much of a burden as you might expect! And, again in 2013, the FDAAA will sponsor a luncheon featuring the FDA Commissioner. Instead of a "Spring Fling," this year it will be a "Summer Fling." But whenever it has been held, it has been a real feel-good event for both the Commissioner, her staff, and the FDA alumni.

There are many more opportunities to play a role in your FDA Alumni Association, and I would encourage you to contact me if you have any interest --- communications, member services, history, activities --- we can always use an extra hand.

There is one area of ongoing concern to which I must direct your attention. In 2012, we undertook a massive effort to take a look at our members and the dues paying process. The Board decided to switch to a calendar year dues schedule, meaning everyone will be on the same January-December cycle. We began phasing this in last year, and will continue through 2013 until all members are on the new schedule in 2014. Members will receive invoices to take any ambiguity out of the process. But at the end of it all, if a member is not paying dues, the membership will become inactive and we'll no longer send the newsletter. You can prevent all of that with a timely response when you receive your invoice!

F. Alan Andersen, President

The Year in Review – Highlights of FDAAA Activities

FDAAA Receives Prestigious Frances O. Kelsey Award

The Association was honored to receive the prestigious ***Frances O. Kelsey Award for Excellence and Courage in Protecting the Public Health*** at an October 2, 2012 FDA ceremony marking the 50th anniversary of the passage of the 1962 Kefauver-Harris Amendments to the 1938 Federal Food, Drug, and Cosmetic Act.

The FDA created the award in 2010 in honor of Dr. Frances O. Kelsey, who was also its first recipient at age 96. Not long after she joined the agency in 1960, Dr. Kelsey became a national heroine because of her fateful decision to withhold approval for the thalidomide sleeping pill in the U.S., a drug soon linked to scores of birth defects throughout Europe. She went on to play a key role in shaping and enforcing the Kefauver-Harris Amendments, which gave the agency authority to require additional testing of new drugs to demonstrate their effectiveness. Dr. Kelsey retired from the FDA in 2005 at age 90.

"We decided, moving a little bit afield from the original vision for the Frances O. Kelsey Award, that we would award it to the FDA Alumni Association," said FDA Commissioner Dr. Margaret Hamburg, at the October 2 commemoration held at FDA's Headquarters in White Oak, MD. Dr. Hamburg presented the Award to FDAAA as an acknowledgement of the "many contributions that have been made by people who have worked hard during their tenure at the FDA, continue to support the FDA in critical ways now but today are a part of the FDA Alumni Association."

FDAAA Chairman of the Board, Joseph Levitt and FDAAA President Alan Andersen received the award on behalf of the Association.

FDA Commissioner Dr. Margaret Hamburg presents ***The Frances O. Kelsey Award for Excellence and Courage in Protecting the Public Health*** *to FDAA President Alan Andersen and FDAAA Chairman of the Board Joseph Levitt.*

FDLI and FDAAA Commemorate the 50th Anniversary of the Drug Amendments Act of 1962

On Wednesday, October 17, 2012, the Food and Drug Law Institute (FDLI) partnered with the FDAAA to host a reception to commemorate the 50th anniversary of the 1962 Kefauver-Harris Drug Efficacy Amendments.

The event was well attended by over 100 members of the food and drug community, including FDAAA members former Bureau of Drugs Director, J. Richard Crout, M.D., and former Director of Drugs Compliance, Dan Michels.

After a welcome by FDLI President Susan Winkler, FDAAA Chairman Joe Levitt gave opening remarks, quoting Dr. Crout as saying the 1962 Drug Amendments were "transformational" for the practice of medicine by their impact on how drugs are developed, and a great example of "regulation gone right!"

Mr. Levitt then stated how honored the FDAAA was to have recently received from FDA Commissioner Margaret Hamburg the Frances O. Kelsey Award for Excellence and Courage in Protecting the Public Health, and how that made this anniversary all that more special. The Kelsey Award is the Agency's highest Award. (http://fdaaa.org/activities/2012/100912.php).

The event featured short lectures by FDAAA member Peter Barton Hutt, Senior Counsel at Covington and Burling and Robert (Bob) Temple, M.D., Deputy Director for Clinical Science, Center for Drug Evaluation and Research. Peter Barton Hutt traced the transition of FDA statutory authority and policy for the regulation of new drugs from the Federal Food, Drug, and Cosmetic Act of 1938 to the Drug Amendments of 1962. He described the legal strategies that his predecessor as FDA Chief Counsel, William W. Goodrich, and he used to establish a strong regulatory structure for implementation of the 1962 Amendments.

Dr. Temple spoke about how FDA revolutionized the quality of adequate and well-controlled clinical trials through experience and agency guidance, making drug effectiveness something patients could rely on.

A reception followed.

FDAAA Celebrates Receipt of Frances O. Kelsey Award

To celebrate FDA's recognition of past contribution of its employees the FDAAA celebrated he Frances O. Kelsey award, along with the holiday season, at a reception on December 6, 2012.

FDAAA Board Chairman, Joe Levitt, reminded the 80 some attendees that he had gladly participated in the FDA's celebration of that 50 year anniversary, but that he had been totally surprised at the Kelsey award being given to the alumni association. On reflection, he indicated he better understood that the recognition should honor all past FDAers who worked so hard and overcame so many obstacles to implement that legislation. He thanked the Commissioner for making us all feel truly valued and appreciated.

Commissioner Hamburg attended the event and her remarks addressed the unique relationship between the FDA and its alumni, in which there is a remarkable shared vision of the program needs, the mission, and the vision of the agency. After the event she commented to Joe: "I am so glad that you did this event and that I could participate. The spirit and warmth in the room was palpable. A good time for an upbeat occasion!"

The event also served as a platform for former Bureau of Drugs Director, Dr. Richard (Dick) Crout to capture the remarkable transformation of the regulation of drugs set in motion by the 1962 legislation. Dick concluded by saying:

"I thank and honor each of you who have worked on any or all [aspects of implementing the 1962 amendments].

I have had a number of jobs in my life-in academia, in the private sector and in government. I enjoyed them all. But head and shoulders better than all the rest was my time at the FDA. It was the hardest job I ever had, but also the most interesting and most satisfying. No career is more enjoyable and more honorable than public service. This is the bond we all share as members of the FDAAA.

...we brought character to the exercise of the power given us by the Congress in 1962, Let us also hope that we brought vision, dedication and humility to this task. Finally, let us hope that those who have replaced us will serve the nation even better than we tried to do. Their journey, like ours, will be worth doing."

In commenting on these remarks, FDAAA President Alan Andersen said, "Joe Levitt and I both share the sense that this is what all FDAAA members feel, but no one has ever said it better!"

This event would not have been possible without the generous support of the following corporate sponsors: the Personal Care Products Council/Cosmetic Ingredient Review, Hogan Lovells, Catalyst Healthcare Consulting, EAS Consulting Group, LLC, Alston & Bird, Greenleaf Health, and Covington & Burling.

FDA Officials Speak at FDAAA Luncheons

The Activities Committee organized three luncheons during the twelve months covered by this report. As in past years, various FDA management staff shared their insights with FDAAA members on how FDA is dealing with the many challenges facing the Agency today.

Jeanne Ireland
Associate Commissioner Office of Legislation

Jeanne Ireland, Associate Commissioner of the Office of Legislation was guest speaker at an August 1st luncheon held at the Rosa Mexicano Restaurant in downtown Washington. This new venue is part of an effort to see what impact location will have on attendance. In prepared remarks, Associate Commissioner Ireland provided an overview of the recently enacted FDA Safety & Innovation Act, which included reauthorization of the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA), along with the passage of the first user fee programs for generic drugs (GDUFA) and biosimilars (BSUFA); she also highlighted the efforts of the many stakeholders involved in FDASIA, including FDA, industry, Congress and patient and consumer organizations.

Mary Lou Valdez
Associate Commissioner For International Programs

The November 7th Alumni Association White Oak luncheon featured Mary Lou Valdez, Associate Commissioner for International Programs and Director of the Office of International Programs (OIP), who provided an overview of FDA's work in addressing and facilitating globalization, noting that the Agency is working to help form coalitions to help other countries develop and expand their regulatory capabilities. She also touched on an Institute of Medicine report released earlier this year that identified gaps in the regulatory systems of developing countries and she discussed FDA's 2011 report that lays out the Agency's strategic plan for addressing the challenges related to globalization.

The FDAAA held another "Brown-Bag" luncheon at the FDA White Oak Campus on March 7, 2013. Richard Pazdur, M.D., Director, Office of Oncology and Hematology Drugs, CDER was the luncheon speaker and provided a brief history of development of oncology drugs. In the late 1970s, the National Cancer Institute had the major focus on oncology drugs although, at the time, industry had no major interest in developing oncology drugs since it was considered a small market with many negative issues.

Richard Pazdur, MD
Director, Office of Oncology and Hematology Drugs

Commissioner Hamburg Speaks at 3rd Annual Spring Fling

FDAAA President Alan Andersen reported that the 3rd Annual Spring Fling with Commissioner Hamburg was a great opportunity not only to hear from Dr. Hamburg, but also to have the opportunity for "face time" with her since she spent about 2½ hours with FDAAA attendees.

In his introduction, Alan Andersen thanked Anne Marie Finley for organizing the event, and highlighted 2012 as FDAAA's 10th anniversary. He noted that there is something about the public health mission of FDA that engenders a combination of zeal, camaraderie, loyalty and any number of other character attributes that are key to FDAAA's very existence. Anderson said FDAAA members "give a damn" about the FDA and its mission and are proud of the work that FDA does. He also emphasized the work of Florence Houn and Zili Li with our international network and the new effort to find ex-FDA reviewers to help at the Center for Tobacco Products.

In her presentation, Dr. Hamburg emphasized the ongoing issues of funding, but was optimistic that the various user fee legislation negotiations are going better than might be expected. She expressed her appreciation for the efforts of groups such as the FDA Alliance for supporting resource increases for FDA. Dr. Hamburg highlighted, and then echoed several times, the theme of FDA as a global Agency and the need for partnering with others to be effective. She cited the FDAAA efforts to help the agency by having alumni participate in meetings around the globe when it just wasn't possible for FDA staff to attend.

FDAAA Participates in International Activities

4th Annual Drug Information Association China Meeting, Shanghai, China

At the 4th Annual China Drug Information Association (DIA) conference held May 20-23, 2012 in Shanghai China, the FDAAA International Network (FDAAAIN) ran four important regulatory sessions: "Drug Risk Assessment and Management at US FDA," "Science-based Regulatory Decision-making: Reality or Aspiration? US FDA Experience," "Vaccine Development and Approval for Unmet Needs," and "Implementation of New and Other ICH Quality Guidelines."

Dr. Zili Li (FDAAAIN Co-chair) leads the discussion at the workshop, "Drug Risk Assessment and Management at US FDA,"

4th Annual Workshop on Regulatory Science-Based Decision Making at SFDA's Center for Drug Evaluation, Beijing, China

To further advance the establishment of science-based decision-making process as a foundation for regulatory review decisions in China, the State Food and Drug Administration's (SFDA) Center for Drug Evaluation (CDE) organized, "The 4th Annual Workshop on Regulatory Science-Based Decision-Making," at CDE headquarters on May 25, 2012. The event was co-sponsored by SFDA's China Center for Pharmaceutical International Exchange (CCPIE), and the FDA Alumni Association International Network (FDAAAIN). Dr. FENG Yi, Associate Center Director chaired the workshop and provided a historic perspective on the importance of the annual workshop. Ms. ZHANG Peipei, Acting Center Director delivered an opening remark and attended the workshop with center review staff. In the evening, SFDA/CDE hosted a reception where DR. ZHANG Wei, Director-General of SFDA Department of Drug Registration and Mr. XUE Bing, deputy center director of CCPIE joined CDE leadership team and FDAAA delegation in discussing "Evolution of User Fees at US FDA."

"Vaccines - FDA and Japan Perspectives" Forum at DIA Conference, Philadelphia, Pennsylvania

The FDAAA through its International Network (FDAAAIN) sponsored a Forum on vaccine development at this year's annual meeting of the Drug information Association (DIA) in Philadelphia, PA on June 25, 2012.

Perspectives from the Food and Drug Administration, Center for Biologics Evaluation and Research (CBER) on vaccines development and external communication policies, along with industry views on regulation and vaccine development in Japan were presented.

Dr. Florence Houn, FDAAAIN co-chair, chaired the Forum. In her introductory remarks, Dr. Houn briefly described the importance of continued vaccine development, communications about vaccine safety and efficacy to the public to instill confidence in vaccinations, and the importance of learning about the evolving challenges of vaccine development in Japan.

Speaking on "Japan Update on Vaccine Developments and Regulations," Mr. Yoshikata Furuya (Manager, Regulatory and Vaccine Policy of Merck) described the recent changing regulatory environment in Japan for vaccines and new efforts by the government to encourage vaccination.

Dr. Sara Gagneten (Expert Regulatory Scientist, Office of Vaccine Research and Review (OVRR) at CBER) presented on "CBER Vaccine Regulatory Update." She described general clinical trials requirements, adjuvanted vaccine policy and pathways to approval.

Ms. Maureen Hess (Health Science Advisor, OVRR at CBER) spoke on "FDA's Office of Vaccine Research and Review Considerations on Vaccine Communication." She detailed the various forms of communication FDA/CBER undertakes to address the need to inform the public, including the adoption of social media.

(From Left to Right: Florence Houn (FDAAAIN), Sara Gageneten (FDA CBER), Maureen Hess (FDA CBER), and Yoshikata Furuya (Merck)

Workshop on Building a Professional Regulatory Workforce in Developing Countries, Washington, DC

On September 19, 2012, the Institute of Medicine (IOM) Board on Global Health convened a workshop on recommendations in its consensus study report, "Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad." The workshop focused on the report's Recommendation 6-3 about building a professional regulatory workforce in developing countries. The US FDA solicited input on ways to implement various training models identified in the report and actions that US Agencies should take to advance training and credentialing. Representing the Food and Drug Administration Alumni Association (FDAAA) International Network at the meeting were Drs. Ekopimo Ibia, Chi-wan Chen and Maritza Colon-Pullano. The FDAAA used the opportunity to inform participants of the Association's mission and goals, which include providing training and technical assistance to health authorities interested in establishing or enhancing regulatory systems, especially in emerging and underserved areas of the world. Further, FDAAA highlighted a few of its activities through its International Network and made itself available to partner with FDA as the Agency implements the IOM recommendations. As part of a long-term and sustainable effort at enhancing regulatory workforce in developing countries, FDAAA International Network participants urged the meeting to effectively organize and harness the expertise of the global pool of former regulators.

(From Left to Right: Maritza Colon-Pullano (FDAAAIN), Ekopimo Ibia (FDAAAIN), Katherine Bond (FDA OIP), Mary Lou Valdez (FDA OIP), Chi-wan Chen (FDAAAIN))

APEC's Advanced Workshop of Good Review Practices, Visits China's State FDA Center for Drug Evaluation, Taipei, China

The FDA Alumni Association International Network (FDAAAIN) participated in the Asia- Pacific Economic Cooperation's (APEC) Advanced Workshop of Good Review Practice of Medical Products on November 6-8, 2012 in Chinese Taipei. Approximately 18 economies' regulatory agencies attended. Dr. Jaw-Jou Kang, Director General, Food and Drug Administration, Chinese Taipei, opened the meeting. The meeting participants included regulators from medical product Agencies from Japan, Chinese Taipei, USA, Canada, Thailand, Indonesia, Mexico, Peru, and Singapore. Drs. Chi-wan Chen, Mark Goldberger, Florence Houn, and Zili Li (FDAAA members) presented a session on Critical Thinking and Decision-Making, using both an actual and hypothetical case study to get audience participation.

The FDAAAIN was invited to meet with the Chinese State FDA's Center for Drug Evaluation (CDE) on November 13, 2012 in Beijing, China. Florence Houn and Zili Li, FDAAAIN Co-chairs, along with Mark Goldberger and members from the Center for Innovative Regulatory Science (CIRS) discussed good review practices and training topics.

Group photo of APEC meeting attendees in Chinese Taipei for the Advanced Workshop of Good Review Practices.

Recognized the Outstanding Contributions of Members

The FDAAA Awards Program continues to honor active members with a variety of awards. In addition, we work closely with the 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 Marie Urban.

Marie Urban
Chairman, Awards Committee

The 2012 Award Recipients

FDA Distinguished Alumni Award

The award was presented to:

Nancy Bradish Myers, Co-Chair, FDAAA Activities Committee

The FDA Distinguished Alumni Award is presented to a former FDA employees who left the Agency more than five (5) years ago, who has a continuing and major impact on FDA as a whole, and reflect FDA's values and exemplify an outstanding commitment to meeting the Agency's mission of protecting the public health.

The Harvey W. Wiley Lecture

The lecture was presented by

Steve Usdin, Washington Editor of BioCentury Publications

The 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 in the field 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 the FDA; provide intellectually stimulation, futurist perspective 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 FDAAA Founder's Award

The award was presented to:

Gail Sherman, FDAAA Secretary

The FDAAA Founder's Award is presented to a members who has served with distinction in a leadership capacity who made significant and visible contributions to promoting the growth and/or visibility of the FDAAA; has served more than one term on the Board and in so doing has advanced the organization's goals and mission, and exemplifies the true spirit and intention of the motto: "Serving those who have served".

Volunteer of the Year

The award was presented to:

Carla Moure, Member of the FDAAA Communications Committee

The Volunteer of the Year is presented to a member of good standing of the FDAAA who has made make extraordinary contributions to the growth, viability and image of the FDAAA over a sustained period of time.

Service Recognition Award

The award was presented to:

Debra Rogan, Member of the FDAAA Member Services Committee

The Service Recognition Award is presented to a member who has had a demonstrably positive effect on the growth, operational success and/or public image of the organization.

FDAAA Continues Support for the FDAAA Scholarship Fund

In April of 2006, the FDAAA established the FDAAA Centennial Scholarship Endowment at Temple University's School of Pharmacy. Scholarships are awarded to deserving students in the Master's Degree Program in Quality Assurance and Regulatory Affairs.

In the fall of 2012, five outstanding students were selected to receive this prestigious award.

Those individuals are:

Donald Ertel MT(ASCP) is a Regulatory Officer for the Division of Manufacturing and Product Quality at the FDA's Center for Biologics Evaluation and Research and also a commissioned officer in the United States Public Health Service. LCDR Ertel holds a B.S. Degree in Medical Technology from the University of Maryland. For almost three years, Donald's primary responsibility at the FDA has been performing scientific regulatory review (CMC) of BLAs, PMAs and supplements. He is a qualified lead inspector for CBER performing pre-license and pre-approval inspections for BLAs and supplements. LCDR Ertel has over 20 years of experience working in Quality Assurance and Compliance in and with regulated industries of Blood Banking & Cell Therapy (prior employment at Johns Hopkins Hospital), Biotechnology, and Pharmaceuticals (prior employment at Shire).

Boriana Tserovski - After graduating with a B.S. in Genetics and Psychology from Iowa State University, Ms. Tserovski worked as a microbiologist at the Microbial Food Safety Unit at the USDA on a Hatfield Quality Meats project devising processing strategies to detect and eliminate pathogenic bacteria in meats. While subsequently working as a senior microbiologist in biopharmaceutical testing services at CRL, she pursued graduate courses in advanced diagnostic microbiology. Most recently, she enrolled in courses leading to the Drug Development Certificate in Quality Assurance/Regulatory Affairs offered at Temple University School of Pharmacy to stay in touch with the developments in the field as well to gain understanding of the full picture of drug development. After excelling in the courses required for the certificate, she was accepted into the Master's Program in Quality Assurance and Regulatory Affairs

Laxmi Padmini Kasichayanula is a trained pharmacist and an active participant in the RAPS NY/NJ Chapter. She holds a RAPS Certificate in Pharmaceutical Regulatory Affairs and is currently pursuing a MS degree in Regulatory Affairs from Temple University. Ms. Kasichayanula worked as an Associate Professor in Pharmacology in a recognized pharmacy school in India, where she actively participated in several extramural activities related the role of pharmacy in patient education and disease awareness.

Anshoo Chowdhary is currently a student at Temple University, pursuing her MS in Quality Assurance and Regulatory Affairs. She did her BS in Pharmacy from India and was awarded with the Global Public Foundation Award and scholarships for an Outstanding Academic achievement at the University. As a pharmacy undergraduate, she always wanted to take her education to next level and increase her abilities through an advance degree and more practical exposures. Prior to coming to United States, she worked for a Pharmaceutical company in India. There, she performed a key role in the Total Quality Management team and learnt about the strict quality standards, GMPs involved at every step of the drug development. Since then, she had a deep desire to explore more into this field and broaden her knowledge and scope. Hence, after coming to USA she decided to opt for Temple's renowned QA/RA program, to gain the best knowledge of the Quality and Regulatory world.

Vishalkumar Patel - From India, Mr. Patel completed his Bachelor of Pharmacy degree from Rajiv Gandhi University BEA school of Pharmacy in 2006. He then earned his Bachelor of Pharmacy Honors degree from Nirma University School of Pharmacy in 2010. Currently he is working as a Pharmacy Graduate Intern, while pursuing his Pharmacy practice license in the United States. His professional interests include academia, research, drug regulation and administration which made him pursue the Master of Science in QA/RA at Temple University in 2011. He plans to pursue a career in the pharmaceutical industry. In addition, he has a greater goal of improving access to medicines in developing countries, while also becoming involved in providing health care to underserved areas both in the U.S. and overseas.

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

School of Pharmacy Dean Peter Doukas expressed his gratitude for the continued support from the FDAAA: "The faculty and staff of Temple University School of Pharmacy, as well as the wider University community, thank the FDAAA for their sustained interest and generosity toward our QA/RA graduate program. One of the University's primary missions is to enable students of limited means and different backgrounds to develop their intellectual potential through advanced education. The FDAAA Centennial Scholarship contributes to that goal by helping bright and talented individuals continue their graduate education during challenging economic times. We thank the FDAAA for being cognizant of the collective human interdependence in all of our endeavors. When any of us contributes to a larger social environment, we also contribute to the well-being of our families and selves. Philanthropy strengthens the social fabric and, in this case, helps to mold tomorrow's leaders in the industry and Regulatory Agency."

The FDAAA scholarship is open to current and new students in Temple's OA/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.

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.
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.)

New Chairman for the Member Services Committee

During this past year, Chairperson Suzanne Sensabaugh handed over the leadership of the Member Services Committee to James (Jim) Morrison. Among other things, the Committee is responsible for promoting recruitment of new members to FDAAA, developing the content of promotional literature, managing the process of member applications and maintaining and updating the membership directory. Jim replaces Suzanne Sensabaugh who has chaired the committee since 2010.

James (Jim) Morrison
Chairman, Member Services Committee

Jim joined FDA in 1974 as a PHS Commissioned Officer serving in the Division of Training and Medical Applications of the Bureau of Radiological Health. He continued his service with BRH and subsequently CDRH rising to the position of Director, Office of Training and Assistance. Jim retired in 1995 after completing 30 years of commissioned service.

Following his FDA service, Jim went to work for the American College of Radiology (ACR) ultimately becoming an Assistant Executive Director. In that capacity, he oversaw Member Services for ACR. He retired from that organization in January, 2013.

"We are delighted to have someone with Jim's experience leading member services for the Association," says FDAAA President Alan Andersen.

Interested in Joining the FDAAA?

To apply for membership, print out the application for [http://www.fdaaa.org/files/FDAAAA_Membership_Application.pdf], or request an application form by writing to:

FDAAA
c/o James Morrison
43564 Calamus Creek Court
Leesburg, VA 20176

Dues for Alumni members are $35 for 1 year, $65 for 2 years or $90 for 3 years; and dues for Associate members are $20 for 1 year, $35 for 2 years or $50 for 3 years. A lifetime membership is available for a one-time fee of $300.

Officers

Chairman, Board of Directors – Joseph Levitt
Vice Chairman – Mark Elengold
President – F. Alan Andersen, PhD.
Vice President – Andrew Bonanno
Secretary – C.K. Gund, PhD.
Treasurer – Nicholas Buhay
General Counsel – Scott Danzis, Esq.

Board of Directors

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Andrew Bonanno
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Mark Elengold
Ann Marie Finley
Judy Gushee
Charles Hoiberg, PhD.
Betty Jones, PhD.
Elizabeth D. Krell, PhD.
Joseph Levitt
Nancy Myers
Florence Houn, MD

Committee Chairs

Activities Committee – Nancy Myers and Anne Marie Finley
Awards Committee – Marie Urban
Associate Member Liaison Committee – Vacant
Communications Committee – Edward Steele
Finance Committee – Joe Levitt
Member Services Committee – James Morrison
Nominating Committee – Daniel L. Michels

Associate Member Liaisons

Fredda Shere-Valenti
CDR James Simpson

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