Food and Drug Administration Alumni Association

Serving Those Who Have Served ™

The Annual Report
12th Edition

FDA ALUMNI ASSOCIATION

2013 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*)
- 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*)
- Hogan Lovells, LLP (*www.hoganlovells.com*)
- Temple University School of Pharmacy (*www.temple.edu/pharmacy*)

We especially thank the Communications Committee for keeping records of FDAAA events that serve as the basis of the 2013 Annual Report.

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 Judith Gushee (*jagushee@gmail.com*).

This Annual Report covers the period from the April 2013 Annual Meeting to the April 2014 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

As I complete my two-year term as FDAAA chair, I look back on the two goals I set when I assumed this role in 2012: (1) raising the visibility of the association; and (2) assuring fiscal soundness. I feel proud that FDAAA has made substantial progress to achieving both these goals – and more.

A major highlight of the past two years was in the fall of 2012 when FDA Commissioner Margaret (Peggy) Hamburg presented the FDA Alumni Association with the Frances O. Kelsey Award for Excellence and Courage in Protecting the Public Health. There is nothing more fulfilling than knowing that the agency leadership truly values and appreciates our contributions – past and present -- even long after we have left the agency's payroll. It illustrates the unique kinship that FDA shares with all its alumni, and vice versa.

This theme was reinforced by former FDA Chief Counsel Richard (Rich) Cooper when, in delivering the annual Harvey W. Wiley lecture at the 2013 annual meeting of the Food and Drug Law Institute, he spoke about the unique cohesion of the FDA community. One basis of this cohesion, he explained, was that when FDA'ers retire and move into the private sector, we never lose our respect for the agency's mission and the people who selflessly carry it out on a daily basis. As alumni, our bond with the agency is deep, long-lasting, and impactful. That is something we can and should all be proud of.

Our relationship with the FDA has never been closer or stronger. The Commissioner's "fling" luncheon has become an annual event – whether held in the spring or the fall. We have met personally with Dr. Hamburg to solidify and expand our working relationship. For example, FDA retirees now receive an FDAAA brochure in their official retirement packages. And last fall, we dedicated the Kelsey Award to permanent display at White Oak to showcase the special relationship that we share.

Our membership continues to grow and, with that, the primary basis for FDAAA's fiscal stability. We substantially upgraded our membership/dues collection process, and we are grateful for the number of alumni who have chosen to join on a two-year, three-year and lifetime basis. We are also establishing a New Membership Recruitment Committee to continue to facilitate our expansion. Our finances are buttressed by our monthly luncheons and special event activities, which continue to draw top agency leaders, past and present. We were especially pleased that former FDA Commissioner Mark McClellan spoke at our Holiday reception in December, as did former Bureau of Drugs Director J. Richard Crout the previous year.

I want to highlight several ongoing activities that fulfill our core mission of supporting the FDA. One is our international program, which has grown to provide ongoing education in foreign countries, beginning with a focus on China and recently expanding into Africa as well. A second is an annual presentation by Senior Alumni to the Commissioner's Fellows program on "What I wish I had known…," now being webcast agency-wise. We are also in the process of developing an "FDA Advisor" program with the agency's Office of Regulatory Affairs so that we can share our experiences and assist with mentoring of today's younger leaders on a more personal, one-on-one basis. We share news of all of these activities, and more, in our monthly newsletter to all members.

None of this happens, of course, without the hard work of many people, too many to name here. But let me thank everyone who has contributed to the FDAAA this past year, whether by virtue of being an officer, board member, committee chair, committee member, volunteer, FDA liaison, agency speaker, or just good old fashion dues-paying member. We need every one of you. I especially want to thank Ed Steele for assuming the functions of association president and "keeping the trains running on time." As I pass the Board Chair baton to Nancy Myers, I share my gratitude and pride for the opportunity to continue being part of this wonderful FDA community.

For the year ahead, I have just two words: "Get Involved!" You will not regret it, I promise.

Joe Levitt, Chairman

Report from the President

Edward A. Steele
President

During my first term as President, I am struck by the progress that the Alumni Association has made in serving the needs of our members while providing much needed assistance and support to FDA. In little over a decade, the FDAAA has grown into an active organization that allows members to keep in touch with former Agency colleagues, make new contacts and to keep informed about the issues facing the Agency in today's complex global environment.

During this past year alone, the Association has maintained an active calendar of events that has included periodic luncheons with top FDA managers, we have honored those who continue to contribute to the public health mission of the Agency, we have sponsored technical workshops to educate industry throughout the world, and we have continued our support for the FDAAA Centennial Scholarship Program at Temple University's School of Pharmacy.

Our relationship with FDA has never been stronger. We are actively looking into ways we can help the FDA carry out its consumer protection mission in an era where its responsibilities have far exceeded the resources Congress has provided.

In this annual report we have summarized the specific achievements of the Association during the past year. It is impressive to think that these accomplishments are only made possible through the voluntary contribution of time and efforts of our members. For it is the Board members, Officers and most importantly, the Committee Chairs and their members that allow this organization to do what it does.

Our success going forward will depend on more and more members being willing to get involved in some way. This may include serving on the Board, joining a committee or, actively participating in FDAAA sponsored events. We are currently in need of filling some important leadership positions including, a new Treasurer, the Chairmanship of the Activities Committee and the Member Recruitment Committee. We are always looking for more members to volunteer to participate in the various committees that are so vital to the smooth operation of this organization. For those of you who want to contribute your skills, I invite you to give me a call. I am certain we can put your talents to work.

For those of you who are actively employed or who have previously been employed by FDA and who are not yet members, I extend a warm invitation to become a member of the FDAAA. I am certain you will agree, that the benefits of joining will far exceed the small cost of membership (See page 12 of this report for membership details).

Let me conclude by thanking Joe Levitt and the Board for their leadership, the Officers for managing the daily affairs of the Association, the Committees for keeping things running and, you – our valued members for making 2013 a tremendous success.

Edward A. Steele, President

The Year in Review – Highlights of FDAAA Activities

Held Annual Meeting

The Annual Meeting was held at the Ronald Reagan Building in Washington, DC on April 22, 2013. The meeting began with a welcome from Joseph Levitt, Chairman of the Board, who discussed the success of the Kelsey Award event and the importance of the scholarship program at Temple. The agenda for the meeting included the financial report and updates from the committee chairs.

Transition of Officers

Edward A. Steele was introduced as the new President, taking over for Alan Andersen and Nancy Myers as the Vice Chair, replacing Mark Elengold.

Edward A. Steele

Nancy Bradish Myers, JD

Awards

Certificates of Appreciation were given to the following member for their part in the Kelsey Award Event

J. Richard Crout, MD

Nancy Bradish Myers, JD

Marc C. Scheineson, JD

Anne Marie Finley, JD

The 2013 Volunteer of the Year was given to:

Debra Rogan, MD, MPH

Service Recognition Awards were presented to the following members for their outstanding contributions to the Association:

Andy Bonanno

Dan Michels

The Founder's Award was presented to Alan Andersen serving with distinction as the Association's President and for exemplifying the true spirit and intention of the motto: "Serving those who have served".

F. Alan Andersen, Ph.D.

During the course of the year, The Board meets quarterly to provide direction and guidance to the Association. The Executive Committee consisting of the Officers (Board Chair and Vice Chair, President and Vice President, Secretary, Treasurer and General Counsel) meet monthly to consider all matters of supervision and control of the business, property and affairs of the Association.

Presented the Wiley Award to Richard M. Cooper

Richard M. Cooper

The Wiley Lectureship Award is presented by the FDAAA at the Food and Drug Law Institute's Annual Conference. The lectureship 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.

The 2013 Wiley Award Winner Richard M. Cooper is one of "Washington's Top Lawyers" for Food and Drug law by Washingtonian magazine (December 2011) and one of the "Best FDA Lawyers" (2012). His principal area of practice is food and drug law, particularly relating to medical products and including advising and enforcement (e.g., inspections, warning letters, administrative sanctions, injunction proceedings and criminal proceedings). He was lead counsel in a commercial arbitration that, in 2007, resulted in an award of more than $395 million for his client. Other recent and current matters include litigation over a product-related decision by FDA, defense against a claim of false advertising, defense against claims of improper pharmaceutical pricing and resolution of FDA enforcement actions. As lead counsel, he argued successfully in FDA v. Brown & Williamson Tobacco Corp., 529 US 120 (2000). He has represented clients in congressional and other hearings. His clients have included major pharmaceutical and other consumer products companies.

For a complete copy of his remarks, please click on the link *www.fdaaa.org/files/FDLI_TALK_2013.pdf*

Honored FDA Aumni Dr. Halyna Breslawec

Dr. Halyna Breslawec

The FDA Distinguished Alumnu Award is an FDA-sponsored award for which FDAAA is asked to nominate candidates. Recipients receive a personal letter signed by the Commissioner, plus an engraved crystal bowl. The award is presented at FDA's annual Honor Awards Ceremony.

This year the award was given to Halyna Breslawec, Ph. D. - For developing efficient, effective scientific review approaches, dramatically expanding the Cosmetic Ingredient Review (CIR) program output, and leading industry support of FDA's cosmetics program goals.

Dr. Breslawec served as a regulatory scientist and manager at FDA. She extended her record of scientific review excellence as a manager of the CIR program, significantly expanding the review capacity of the independent CIR safety assessment program. Dr. Breslawec is currently the Chief Scientist and Executive Vice-President at the Personal Care Products Council where she has been an effective advocate for FDA, helping to assure the availability of resources for the FDA cosmetics program and supporting industry outreach to the medical community.

Continued Periodic Luncheon/Receptions to Keep Members Engaged

Nancy Bradish Myers, JD

Anne Marie Finley, JD

Co-Chairs Nancy Myers, Anne Marie Finley along with the members of the Activities Committee organized three luncheons, a reception in Boston and the popular "Fall Fling", a BBQ luncheon with the Commissioner and top Agency Staff.

These events allow members to socialize and hear from various FDA leaders who speak to the many challenges and opportunities facing the Agency today.

Luncheons in the DC Area:

Tom Abrams, Director Office of Prescription Drug Promotion

The Office of Prescription Drug Promotion has a mission "To protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers." Mr. Abrams discussed the OPDP top five priorities and he identified some of the most common observations made by the Division.

Lisa Barclay JD, FDA Chief of Staff

Ms. Barclay provides integrated policy analysis and strategic consultation to the Commissioner and senior FDA officials on significant Agency issues and programs; provides leadership, coordination and management of the Commissioner's priority policies and issues; and serves as the Agency's principal liaison with HHS.

Ms. Barclay stated that she believed that 2013 had been a year of accomplishments, despite some significant personnel departures. She mentioned the following as general themes for the Agency: targeting high risk issues and focusing on preventative programs, and strengthening alignment between headquarters programs and field operations and resources.

Melinda Plaisier, Associate Commissioner for Regulatory Affairs (ACRA)

Mrs. Plaiseir spoke about the Commissioner's focus on globalization and the effort to better align inspection forces within the Centers. Mrs. Plaisier provided excellent insights into the focus of FDA's regulatory efforts and how they are changing to keep up with the complex global environment in which the Agency now finds itself.

Mrs. Plaisier began her career in public policy, working in the U.S. Congress for over a decade. She joined FDA in 1995, spending more than 13 years in the Office of the Commissioner, where she served as the Associate Commissioner for Legislation. She also served as the Associate Commissioner for International Programs, where she focused on negotiating international agreements and working with developing nations. Prior to becoming Associate Commissioner for Regulatory Affairs, she served as the Regional Food and Drug Director (RFDD) for the Central Region.

FDAAA Goes "Outside the Beltway"

In an effort to allow FDAAA members who live outside of the DC area to participate in more Association activities, a cocktail party was held at Lucky's Lounge in Boston on June 25th. This event we held to coincide with the Drug Information Association's (DIA) Annual Meeting which took place at the Boston Convention Center, within blocks of the where the reception was held. 25-30 members attended the event and exchanged war stories from their old days at FDA. From the comments received from those who participated, the idea of bringing FDAAA events out to the "Field" was well received and one that will be repeated in different cities in the future.

The Annual "Fall Fling" Luncheon with the Commissioner

Margaret A. Hamburg, M.D.FACP

2013 is the fourth year this event has been held at the White Oak Campus and almost 80 people gathered in the great room at White Oak for the event. Ironically, this event was held the day before the Congress was unable to agree upon a federal budget and the government was forced to shut down.

That aside, this again was a great event where FDA alumni had the opportunity to enjoy a picnic-style lunch and hear the challenges and opportunities facing the Agency directly from the Commissioner. It gave the participants the opportunity to chat with many of the Agency's top managers.

In introducing the Commissioner, FDAAA President Ed Steele thanked Dr. Hamburg for her support of the Association, noting that "the bond between the FDA and the Alumni Association has never been stronger." He mentioned that as an outcome of a recent meeting with the Commissioner, Dr. Hamburg has appointed Virginia Cox, Associate Commissioner for External Affairs to serve as liaison between her office and the FDAAA. Steele commented that "we are delighted to have Virginia serve in this capacity."

Commissioner Hamburg, was gracious to spend the time to identify the major issues facing the FDA and for sharing her thoughts on how the Agency can use the experience and talents of the FDA alumni. The need to work together comes at a time were the demands are increasing and the Agency resources continue to be constrained.

Alumni Association Placed Frances O. Kelsey Award on Permanent Display at FDA Headquarters.

Immediately following the "Fall Fling" luncheon, a brief ceremony was held to place the Frances O. Kelsey award on permanent display at FDA headquarters.

On October 2, 2012, at the 50th anniversary celebration of the drug amendments, Dr. Hamburg, presented the Frances O. Kelsey Award to the FDA Alumni Association. The FDA created the Frances O. Kelsey Award for Excellence and Courage in Protecting the Public Health 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 hero 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 efficacy.

In presenting the award last year, the Commissioner remarked "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." "FDA employees today are making a huge difference, but as we reflect in a historical context on all that has been accomplished, we also want to recognize FDA employees past," she stated. "I think it is very, very fitting to acknowledge FDA employees current and past in this way," she said.

FDAAA Chairman Joseph Levitt said "there is no more fitting place than FDA headquarters for this award."

Such a placement serves to honor all FDA employees, past and present, whether they are members of the FDA Alumni Association or not, and stands as clear evidence that FDA is an agency that recognizes the contributions of those who have gone before.

Held Reception to Celebrate 75th Anniversary of FFDCA

Dr. Mark McClellan

On December 3, the FDAAA held an end of the year event celebrating the 75th Anniversary of the Federal Food, Drug, and Cosmetic Act (FFDCA). The reception was held at the office of the law firm of Alston and Bird in Washington, DC. Board Chairman, Joe Levitt welcomed everyone, thanked the event organizers and introduced Dr. Mark McClellan, former Commissioner of FDA.

Dr. Mark McClellan discussed the 75th Anniversary of the 1938 Federal Food, Drug, and Cosmetic Act as well as the current and future challenges facing FDA. Dr. McClellan noted that FDA continues to meet its mission of ensuring the safety of the products for which it is responsible even with continuing limited resources. He emphasized the crucial role of the employees of FDA who are dedicated to meeting FDA's mission. These professionals represent a wide array of talent and work continuously to make a difference in people's lives. Dr. McClellan stated that due to limited resources and increasing responsibilities which will no doubt continue into the future, FDA will need to take different approaches to accomplishing the Agency's mission.

Dr. McClellan noted that he was Commissioner when the Memorandum of Understanding was signed between FDAAA and FDA. He acknowledged FDAAA's efforts to help assist and promote the Agency as well as the Alliance for a Stronger FDA which is working to improve the Agency's budget.

The FDAAA International Network Continues to Expand its Reach Globally

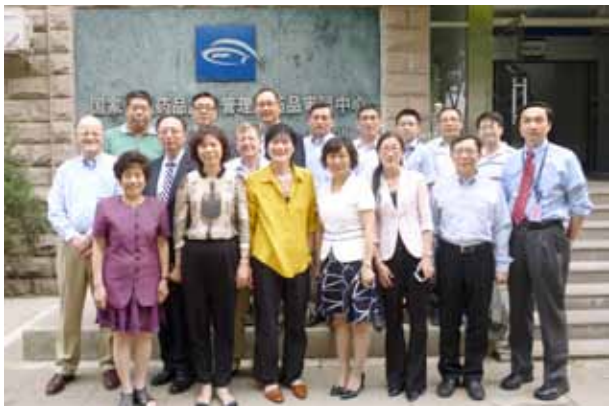
Florence Houn MD, MPH FACP

Zili Li, MD, MPH

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.

During the past 12 months covered by this report the FDAAA International Network has:

- Co-sponsored the 5th Annual Workshop on Regulatory Science-Based Decision Making for China's State FDA's Center for Drug Evaluation on May 17, 2013, Beijing
- Led Eight Major Regulatory Sessions at the 4th Annual Drug Information Association China Meeting on May 13-15, 2013, Beijing
- Held Successful One-Day Clinical Workshop On a Case Study of Benefit-Risk Regulatory Decision-Making with the Center for Drug Evaluation, Taiwan, on May 10, 2013, Taipei
- Hosted a medical device global symposium during the 49th DIA Annual Meeting on June 24-27, 2013 in Boston, MA.
- Sponsors US DIA Session on Health Disparities and Global Trials Data
- Co-sponsored Workshop on Regulatory Harmonization for Consumer Products in Sub-Saharan Africa, Lagos and Nigeria, July 8, 2013
- Spoke at the First Biennial Scientific Conference on Medicines Regulation in Africa held December 2-3, 2013 in Johannesburg, South Africa.



Front Row Left to Right: Chi-wan CHEN, Peipei ZHANG, Florence HOUN, Zhimin YANG, Ning ZHANG, John GONG, and Ning LI
Middle Row Left to Right: Robert Meyer, Duu-Gong WU, Mark Goldberger
Third Row Left to Right: Yi FENG, Dylan (Dalin) YAO, David LIN, Xiaoxiong (JIM) WEI, Jinbo YANG, Jifeng (Jeff) SHI, Qingli WANG, and Cailian KANG.

Dr. Ibia (2nd right) with Dr. Nathalie Strub-Wourgaft, Medical Director, Drugs for Neglected Diseases initiative (DNDi, 2nd left); Mr. Hiiti Sillo, Director General, Tanzania Food and Drugs Authority (right); and other conference participants

To commemorate the 100th anniversary of the Agency, the FDAAA established a scholarship fund in 2006 at Temple University's School of Pharmacy in Philadelphia, PA.

Each year the FDAAA Centennial Scholarship is awarded to students in the Master's Degree Program in Quality Assurance and Regulatory Affairs (QA/RA) at Temple University. It consists of the tuition cost for one QA/RA graduate course (exclusive of any applicable University fees.) The FDAAA scholarship is open to students who pay out-of-pocket for their education and do not receive tuition reimbursement from an employer. The scholarship is awarded on the basis of financial need and academic merit.

Since 2006, fifteen outstanding individuals, working in the industry and government, have received full or partial FDAAA scholarships. All have expressed their deep appreciation to the FDAAA for helping them achieve their goal of pursuing a graduate degree to advance their careers in drug discovery, regulatory compliance, quality assurance and safety, and scientific advancement.

Donations for the Scholarship fund, over the last 12 months have totaled $5,680. Rather than apply these donations to scholarships the University is using them them into build up the endowment, which currently stands at $69,818. At today's interest rates the interest on the endowment would only produce 1 partial scholarship award. Yet in 2013 Temple's School of Pharmacy awarded scholarships (three partials and two full; at a total value of $8,800. Until the endowment grows and interest rates improve, the students are receiving the FDAAA scholarship but the University is footing the bill.

With a larger endowment, the FDAAA Centennial Scholarship could aid additional students, helping them to achieve their career potential. Each year deserving students must be turned away due to limited funds. Please consider giving to the scholarship to help support tomorrow's leaders in the U.S. FDA and the pharmaceutical and related industries. The gift of education continues to be a profound change agent that has the power to transform lives.

For more information please contact:

Christopher Van Vessem, Director of Development
School of Pharmacy, Temple University
3307 North Broad Street
Philadelphia, PA 19140
Phone: (215) 707-9457, email: christopher.vanvessem@temple.edu

Contributions can be made by check or credit card:

Credit Card Donation: Can be made on the FDAAA website via PayPal - *www.fdaaa.org/centennial_scholarship_award.php*

The 5 recipients of full or partial FDAAA scholarships in 2013:

Donald Ertel

Donald Ertel MT(ASCP) is a Regulatory Officer for the Division of Manufacturing and Product Quality at the FDA's Center for Biologics Research and Evaluation 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). When he is not performing duties to promote and protect the health and safety of our nation, Donald is pursuing nonstop activities with his wife and three daughters or his musical endeavors as a tenor in the USPHS Choral Ensemble and bass player. Having received the certificate in Drug Development, Donald is truly grateful and honored to receive this award, and is thrilled to continue his pursuit of the QA/RA Master's degree at Temple.

Ding Ding

Ding Ding received a bachelor's degree in Chemistry from Peking University in China before coming to the United States to pursue a master's degree in Chemistry from the Catholic University of America in Washington, D.C. Her career in the pharmaceutical industry started as a scientist at DuPont Pharmaceuticals. Upon joining Pfizer, she initially worked as a Bioanalytical Analyst, developing and validating bioanalytical assays for GLP studies and clinical trials for regulatory submissions. She then became a Regulatory Document Specialist, working within the Submission, Toxicokinetic, and Reporting Group focusing on Pharmacokinetics, Dynamic and Metabolism. While working at Pfizer, she received the company's Individual Performance Award eight times, a distinction that recognizes exceptional performance and excellent leadership. Currently enrolled in the QA/RA graduate program, she has already applied her coursework knowledge to the writing of regulatory reports and documents for submission and to the increased awareness of how global clinical trials are conducted. Ding finds the flexibility of the QA/RA program supports her ability to juggle her time between a professional career, family and two small children.

Margery Dillenbeck

With an MS degree in both nursing and education, Margery is licensed as a registered professional nurse and as a nurse practitioner in family health. She is also certified as a public school teacher, having majored in Special and Elementary Education. In her professional nursing career, she has achieved Level III critical care nurse status (the highest level of achievement as a staff nurse), which has proved to be invaluable experience for her subsequent work as a member of global product surveillance teams at pharmaceutical companies. In particular, she learned first-hand about the critical importance of diligent investigation of side effects when she served as a contract worker for Bausch & Lomb and witnessed the recall of ReNu ML. Currently, she assesses adverse events for both pre- and post-market products as a Drug Associate for Lundbeck, Inc., which specializes in CNS disorders. Residing in Rochester, NY, with her husband and four children, Margery is pursuing Temple's QA/RA program to enhance her knowledge of pharmacovigilance.

Vishalkumar Patel

From India, Mr. Vishalkumar 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 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. He wishes to thank the FDAAA for their scholarship and also wishes to thank his family, friends, and mentors for their continued support and encouragement.

Jillian Carinci

A Senior Specialist at Accenture (formerly Octagon Research Solutions) in the Regulatory Operations department, Jillian holds a degree in Chemistry with a minor in Mathematics from Lafayette College. For the past five years, Jillian's career work has focused on building eCTD submissions including NDAs, INDs, MAAs, and CTAs. She serves as Project Manager on multiple client projects including eCTD submissions, document formatting, SPL, and submission readiness. Having seen first-hand how adverse events affect patients, she believes patient safety should always be the driving goal during drug development. She says her Temple University classes have given her an overview of the drug development process and enabled her to perceive issues beyond her specific niche. As her company expands globally, she is already putting into practice the principles she has learned in Temple classes. She will finish her Masters in QA/RA in December 2013.

Interested in Joining the FDAAA?

To apply for membership, print out the application *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, JD

Vice Chairman – Nancy Myers, JD

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Vice President – Andrew Bonanno

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Betty Jones, PhD.

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Florence Houn, MD

Committee Chairs

Activities Committee – Nancy Myers, JD and, Anne Marie Finley, JD

Awards Committee – Marie Urban

Associate Member Liaison Committee – Vacant

Communications Committee – Judy Gushee

Finance Committee – Liz Krell, PhD

Member Services Committee – James Morrison

Member Recruitment Committee - Vacant

Nominating Committee – Stephen Sundlof, DVM., PhD.

Associate Member Liaisons

Fredda Shere-Valenti

CDR James Simpson

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