Food and Drug Administration Alumni Association

Serving Those Who Have Served ™

The Annual Report
13th Edition

FDA ALUMNI ASSOCIATION

2014 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*)
- Biogen Idec (*www.biogenidec.com*)
- Biotech Policy Group
- 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*)
- Fox Kiser (*www.foxkiser.com*)
- Greenleaf (*www.greenleafhealthllc.com*)
- Hogan Lovells, LLP (*www.hoganlovells.com*)
- King & Spalding (*www.kslaw.com*)
- Temple University School of Pharmacy (*www.temple.edu/pharmacy*)

Thank you to FDAAA member Pam Pisner for helping to compile this report and to Jason Steele for designing the Annual Report.

This Annual Report covers the period from the April 2014 Annual Meeting to the April 2015 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

Nancy Myers
Chairman

How could a year have flown by so fast? It has only been 12 months since Joe Levitt presented me with the Chairman's gavel and yet it seems like a blink of an eye.

With the help of the Executive Committee and the Board, in 2014 we identified three goals to continue to propel FDAAA in the right direction: 1) boost member activities to increase the value of being part of our alumni community, 2) expand our interactions and relationship with FDA, and 3) ensure FDAAA has both the human and financial resources to accomplish the Board's lofty goals.

As noted in Ed Steele's thoughtful President's message, we made significant strides in 2014 to accomplish our three objectives. FDAAA continues to organize lectures, panels and programs to lend our expertise to FDA. We 've co-sponsored international meetings like DIA's China meeting in Beijing and commented on draft model legislation in Africa. We organized unique get together events like lunches and even a cocktail reception to celebrate Center Directors current and past. We are also updating our website and engaging in a new membership recruitment campaign to strengthen the organization.

However, as Chairman my job is not to peer into the glow of the rear-view mirror. Rather, with the support of the Board, I need to make sure there is plenty of gas in the tank, and ensure we are headed in the right direction. The gas in 2015 will be engagement!

This letter is a solicitation for even more enthusiastic volunteers. We need the bright ideas and energy of additional volunteers in the DC & MD area; however, to reach our goal of being more national, we will need volunteers from around the country to expand our activities no matter where our alumni live. There are plenty of opportunities to engage at a level that is just right for the amount of time you have to offer the organization. If you are interested in participating more, please contact anyone on our Membership Committee or other Commitees and discuss which activities will be both fun and meaningful to you.

So my mantra this year is ENGAGE.

- Engage with us, no matter how big or little your time commitment is.
- Your engagement will lead FDAAA to generate more activities, and allow them to flourish.
- One specific area we want to grow is our engagement with FDA and foreign regulators.
- Most importantly, your engagement will allow us to engage more with each other and keep fresh those relationships we hold dear.

So, thank you for taking the time to read our annual report. Please consider getting more involved with FDAAA. We need you and want you to participate!

Thanks,

Nancy Myers, FDAAA Chair

Report from the President

Edward A. Steele
President

This past year has been a great year for the FDA Alumni Association. It has been a year when our new committee chairmen worked hard to begin to increase membership and offer more services to all of our associate and alumni members, not just those in the DC area. Recognizing that membership in the FDAAA is open to current FDA employees and these are the folks that will be tomorrow's alumni, it has been a year of increased attention on spreading the word about the FDAAA to current FDA employees.

The FDAAA has grown into an active organization that allows members to keep in touch with current and 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, the Association maintained an active calendar of events. We have sponsored periodic luncheons with top FDA managers. We have honored those who continue to contribute to the public health mission of the Agency. We have worked to provide educational and technical support to FDA. We sponsored technical workshops to educate industry throughout the world. And we have continued to provide scholarships to deserving students at Temple University's School of Pharmacy through the FDAAA Centennial Scholarship Program.

The "Commissioner's Spring Fling" luncheon and our "Tribute to Center Directors – Past and Present" reception were the social highlights of the year. Both were great events that allowed alumni and current FDA management and staff to interact in a relaxed social atmosphere. Also particularly noteworthy is that the FDAAA gave the Harvey W. Wiley Award, its most prestigious external award, to Dr. Robert Temple. Over the past ten years, this award has been given to former Commissioners, Members of Congress, journalists, and others, but never to someone still employed at FDA like Dr. Temple.

Our relationship with FDA improves each year, thanks to a large extent to the interest and support of Commissioner Margret Hamburg. Since Dr. Hamburg is leaving the Agency, I speak on behalf of the entire Alumni Association in wishing her well in her future endeavors and thank her for her strong support of the FDAAA during the past six years. We invite her to become a member of the Association as she enters the alumni ranks. And we look forward to working with the new Commissioner in the future.

We continue to look for 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 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 are actively employed and/or who have previously been employed by FDA and who are not yet members, I extend a warm invitation to you 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.

Let me conclude by thanking Nancy Myers 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 2014 an outstanding year for the FDAAA.

Edward A. Steele, FDAAA President

The Year in Review – Highlights of FDAAA Activities

Annual Meeting

The Annual Meeting was held on April 22, 2014 at the Ronald Reagan Building and International Trade Center in Washington, DC. 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.

Awards

Certificates of Appreciation were given to Marie Urban and Nicholas Buhay.

Marie Urban

Nicholas Buhay

The 2014 Volunteer of the Year was given to the FDAAA International Network

Florence Houn MD, MPH

Zili Li, MD, MPH

The award was given to Florence Houn MD, MPH, FACP and Zili Li, MD, MPH co-chairman of the committee (pictured above) and the following members:

- Catherine W. Carnevale, VMD
- Chi-wan Chen, Ph.D.
- Funmilayo O. Ajayi, PhD, FCP
- Ekopimo O. Ibia, MD, MPH
- Jinjie Hu Ph.D.
- Kaiser J. Aziz, PhD, FACB, FACS
- Maritza Colon-Pullano
- Nancy Bradish Myers, JD
- Oluwole Odujinrin, MD, MPH
- Walter Batts

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

Karen L Carson

Anne Marie Finley

C.K. Gund

James L Morrison

Nancy Bradish Myers

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

Joseph A. Levitt, JD

Mr. Levitt has served on the FDAAA for two consecutive terms and was appointed to Chair the Board in 2012. He did an outstanding job in directing the policies and direction for the Association.

Wiley Award Presented to Robert Temple, MD

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.

Nancy Myers, Robert Temple, MD and Edward Steele

The 2014 Wiley Award Winner is Robert Temple, MD. Dr. Temple serves as CDER's Deputy Center Director for Clinical Science and also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). He has served in this capacity since the office's establishment in 1995.

Dr. Temple received his medical degree from the New York University School of Medicine in 1967. In 1972 he joined CDER as a review Medical Officer in the Division of Metabolic and Endocrine Drug Products. He later moved into the position of Director of the Division of Cardio-Renal Drug Products.

In his current position, Dr. Temple oversees ODE-1 which is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple has a long-standing interest in the design and conduct of clinical trials. He has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control trials, trials to evaluate dose-response, and trials using "enrichment" designs.

FDA Honored Alumni Dr. Florence Houn and Dr. Zili Li with the Distinguished Alumni Award

The FDA Distinguished Alumni 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.

Commissioner Margaret Hamburg, Florence Houn, MD, MPH, FACP Zili Li, MD, MPH and Edward Steele

This year the award was given to Florence Houn, MD, MPH, FACP and Zili Li, MD, MPH. Dr. Houn and Dr. Li are co-chairs of the FDAAA's (FDAAA) International Network (FDAAAIN). Drs. Houn and Li founded the FDAAAIN in 2009 as an activity to fulfill the FDAAA's bylaws mission of "to sponsor humanitarian outreach programs that entail training and technical assistance to health authorities interested in establishing or enhancing national regulatory systems in order to improve the health and social conditions of underserved nations and regions of the world." Dr. Houn and Dr. Li have:

- Established and recruited a planning group (10 members) with monthly meetings to develop strategy and projects
- Developed SOPs for operations: clearance of slides, use of disclaimers on materials, and policies with regard to dissemination of international opportunities to interested FDAAA members
- Developed and implemented a strategy for African and Asian regulatory capacity building based on the conduct of educational activities in regulatory science to promote regulatory capacity building and the FDAAA as an international resource
- Established ties with the Office of International Programs at the FDA,
- Worked to promote FDAAA standing through collaborative activities with DIA, FDA, RAPS. APEC RHSC, WHO, NEPAD, and other organizations,
- Developed educational programs and conducted these in Africa and Asia.

Dr. Florence Houn is Celgene's Vice President, Regulatory Policy and Strategy, having joined in August, 2008. Prior to this, she served 15 years in the US Food and Drug Administration (US FDA), most recently as Deputy Director for the Office of Vaccines Research and Review in the Center for Biologics Evaluation and Research (CBER). In recognition of her contributions to public health, Dr. Houn received the US Department of Health and Human Services' Career Achievement Award in January 2009. From 1999 to 2006, Dr. Houn was the Director, Office of Drug Evaluation III in the Center for Drug Evaluation and Research (CDER). She served as a Deputy Director for the Office of Drug Evaluation II in 1998, and from 1993-1998, was the Director for the Division of Mammography Quality and Radiation Programs in the FDA's Center for Devices and Radiological Health (CDRH). Dr. Houn

was on the PDUFA V industry negotiating team with FDA in 2010-2011. Dr. Houn is the co-chair of the FDA Alumni Association's (FDAAA) International Network (FDAAAIN) and has been a member of its Board of Directors since 2012. She served as FDAAA Treasurer from 2009-2012 Dr. Houn received her Bachelor of Arts degree from Harvard University and her medical degree from the Albert Einstein College of Medicine. She completed her Cancer Prevention Fellowship at the National Cancer Institute and obtained her Masters of Public Health from the Johns Hopkins School of Hygiene and Public Health. She attended the Johns Hopkins Breast and Ovarian Surveillance Service as an Instructor in Oncology.

Dr. Li is currently deputy director, R&D, at China Office of Bill & Melinda Gates Foundation, responsible for managing and overseeing all local R&D, regulatory and manufacturing efforts in supporting the foundation's global strategic programs and local initiatives across human and animal health, agricultural development, and water sanitation & health. Dr. Li was a medical team leader with US FDA/CDER, overseeing the clinical review of IND and NDA applications of new drug products. Dr. Li also participated in development of FDA's guidance to industry, presented at FDA's advisory committee meeting on behalf of the agency, and was a recipient of many FDA awards, including 2003 FDA Scientific Achievement Award. Dr. Li, a board- certified physician in Preventive Medicine and graduate of Peking Union Medical College, completed his residency training at the Johns Hopkins University. In addition to his medical degree, Dr. Li also holds two master degrees in public health. Dr. Houn was on the PDUFA V industry negotiating team with FDA in 2010-2011.

Periodic Luncheon/Receptions to Keep Members Engaged

Co-Chairs Deborah Henderson and Jayne Ware, along with the members of the Activities Committee, organized the popular "Spring Fling" (a BBQ luncheon with the Commissioner and top Agency Staff), and a luncheon where CDERs Deputy Center Director for Science Operations Richard Moscicki, M.D., was the featured speaker. In addition they organized an end of year reception honoring past and present Center Directors. These events allow members to socialize and hear from various FDA leaders who speak to the many challenges and opportunities facing the Agency today.

Fifth Annual FDAAA Spring Fling - May 27, 2014

Commissioner Margaret Hamburg

We held the annual Spring Fling with Commissioner Margaret Hamburg on May 27 at the FDA White Oak Campus. In her introduction of Commissioner Hamburg, FDAAA Chair Nancy Myers mentioned that this was the fifth annual Spring Fling which was started to welcome the Commissioner to her then new job.

Commissioner Hamburg reflected on the work during her five years at FDA. She stated that this has been a period where FDA has repositioned itself in some critical ways for the 21st century as a unique, science-based, data-driven regulatory Agency with a public health mission. Dr. Hamburg remarked that FDA Alumni are increasingly providing critical support for the Agency.

During the past five years, FDA has developed and institutionalized new models for doing business and for transparency. FDA now has a number of public/private partnerships in areas such as biomedical science and food safety and nutrition which have helped the Agency to be prepared for new products entering the marketplace. FDA found that as the Agency has changed in these ways, that they have been able to have increased budgets which helps do the job well. In a recent poll, FDA went up the most among government agencies in public trust and confidence.

Bi-partisan support for legislation such as the Food Safety Modernization Act has been helpful for the Agency. Commissioner Hamburg said that the Agency is in a critical phase - starting implementation of new rules in the next few years will be crucial in achieving Agency success.

In closing, Commissioner Hamburg stated that the Agency is working hard to strengthen science in FDA and underscore the role of science in everything FDA does.

September 14 Luncheon with CDER Deputy Center Director for Science Operations, Richard A. Moscicki, MD

Nearly 30 FDAAA members had the pleasure of meeting Richard Rich Moscicki at the September 14 FDAAA Luncheon.

Dr. Moscicki is CDER's Deputy Center Director for Science Operations. As a long-term leader in the pharmaceutical industry, Dr. Moscicki was able to provide a unique perspective on current activities in CDER by adding a flavor of his personal experience in adjusting from private industry to a public service leadership position.

Dr. Moscicki joined FDA in February 2013 after a long career with Genzyme Corporation which culminated with his position as senior vice president and head of clinical development at Genzyme. Now, as a deputy Center Director in CDER, an organization of over 4,000 employees, Dr. Moscicki shares in the executive direction of the Center as well as leadership in overseeing CDERs many programs.

The primary focus of Dr. Moscickis remarks to the group was a general characterization of the current priorities for CDER. At the outset, he acknowledged that, as former FDA employees, he knew his audience was well aware of the phenomenon of shifting priorities at the Agency. With pressure on the Agency from all directions...the Administration, Congress, the courts, industry, patient and consumer groups...a priority is a priority until something of higher priority shows up!

Against that backdrop, Dr. Moscicki shared his insight and highlighted many of the current priority issues the Center is managing. At the top of the list is implementation of the Generic Drug User Fee Act requirements, including staffing up the Office of Generic Drugs (with a staggering 600 new hires!), establishing the organizational structure and processes for meeting the negotiated review timelines for generic drug applications, eliminating the backlog of abbreviated new drug applications, and building the information technology (IT) infrastructure needed to support the program.

Next on the list was the establishment of the Office of Pharmaceutical Quality in CDER. Significant energy and resources are being spent on strengthening the regulation of quality manufacturing, encouraging manufacturers to enhance their quality management systems

and quality metrics, building an inspectorate in the field that will specialize in inspections of pharmaceutical manufacturing facilities, and getting CDER and the field (ORA) on the same IT systems.

And, as usual, new topics do get added to CDERs priorities. In addition to these major efforts, Dr. Moscicki recounted a remarkably extensive list of other significant policy and operational topics the Center is facing.

Dr. Moscicki was extremely generous with his time and fielded questions from the attendees, who were very interested in hearing his thoughts on various activities happening in CDER. This aspect of FDAAA events continues to be one of the most valuable for FDAAA members.

FDAAA Holds End of Year Reception as a "Tribute to Center Directors – Past and Present"

About 100 members of the FDAAA gathered on Tuesday November 18 in downtown Washington to recognize and honor former and current directors of FDA centers. Fourteen center directors attended.

Nancy Myers, FDAAA chairperson, who MCed the event, noted the important role that center directors play at FDA, by providing leadership and direction for programs including product approvals and compliance. Ed Steele, FDAAA president read the following remarks from Commissioner Margaret Hamburg who was unable to attend in person:

I am sorry that I could not attend the tribute to FDA's Center directors past and present, due to my long planned trip to China. However, I want to pass along my personal appreciation for the contribution our Center directors have made and continue to make to our nation's health and well-being. Before becoming FDA's Commissioner, I had a broad, but incomplete appreciation – like that of many Americans – for FDA's role in what is often called out consumer product "safety net." My five-plus years at FDA have given me a much fuller understanding of how remarkable FDA is as an institution that protects all of us every single day. And the range of roles and responsibilities that the Center directors have taken on over the years is nothing short of extraordinary. While the FDA is comprised of thousands of truly dedicated people, it is the Center Directors that provide the critical leadership their employees need to realize those exceptional achievements. You are all singular leaders and my respect for your accomplishments is boundless. You are genuinely awe inspiring. Thank you so much for all you have done year after year and for being – in so many ways – the heart and soul of the Food and Drug Administration.

The gathering was held at FoxKiser, a law firm in downtown DC. Sponsors of the event included FoxKiser, Biogen Idec, Greenleaf Health, Hogan Lovells, Keller & Heckman, King and Spalding, Alston & Byrd, Catalyst Healthcare Consulting and, Biotech Policy Group.

The event is part of a series sponsored by the FDAAA to recognize leaders at the FDA and to provide an opportunity for FDAAA members to gather in an informal setting with friends and former colleagues.












FDAAA joins FDA in recognizing the 100th birthday of one of the Agency's most celebrated alumnus

The FDAAA joined FDA in recognizing the 100th birthday of one of the Agency's most celebrated alumnus. Her contributions are a source of great pride to all those dedicated to the FDA mission.

The following appeared in the FDA Voice on July 24, 2014 (*FDA Voice – Dr. Kelsey*):

Dr. Frances Kelsey, Who Protected Americans from Thalidomide, Turns 100

By: John Swann, Ph.D., an Historian at FDA

Frances Kelsey, Ph.D., M.D.

Today marks the 100th birthday of one of America's most celebrated public servants. Frances Oldham Kelsey, Ph.D., M.D., was born in Cobble Hill, Vancouver Island, British Columbia, and earned her Ph.D. in pharmacology and her M.D. at the University of Chicago. She was on the faculty of the University of South Dakota and practicing medicine when, in 1960, she accepted the offer to become a medical officer at FDA.

A month after assuming her position she was assigned the review of a new drug application for thalidomide, a sedative that had been used by expectant mothers and many others in dozens of countries since the late 1950s. U.S. law at the time required a firm to provide evidence of a drug's safety as a requirement for sale. Despite the global popularity of this drug, and despite a constant and increasing pressure from the firm to approve the application, Dr. Kelsey refused to do that without adequate evidence that the drug was safe, a decision that was supported by her colleagues and superiors.

By late 1961 scientists discovered that thalidomide was responsible for crippling birth defects in thousands of babies in many parts of the world. Thanks to Dr. Kelsey's "exceptional judgment in evaluating a new drug" - as her firm stand was described in the President's Award for Distinguished Federal Civilian Service she received from President John Kennedy - the U.S. was mostly spared the tragedies. But the close encounter with a public health catastrophe convinced Congress and the White House to resuscitate proposals to revitalize the regulation of pharmaceuticals. The result was the 1962 enactment of the Kefauver-Harris Drug Amendments that mandated "substantial evidence" of a drug's effectiveness as developed by "experts qualified by scientific training," in addition to evidence of a drug's safety, and provided for greater oversight of drug investigations. These and other requirements in the new law established a global standard for the evaluation of drugs.

After 1962, Dr. Kelsey oversaw the evaluation of investigational drugs and, later, of oncologic drugs and radioisotopes. Concerns in the agency with problematical clinical investigations continued in the early 1960s, such that FDA created the Division of Scientific Investigations in 1967 and placed Dr. Kelsey in charge. She remained in this position until 1995. The division engaged in inspections of clinical investigators, animal studies, and institutional review boards involved in drug trials. Thus, Dr. Kelsey helped ensure the reliability of data vital to FDA's evaluation of therapeutic products over a span of four decades.

Frances Kelsey, the recipient of the highest honor that can be bestowed on a federal civil servant, officially retired from FDA in 2005, but her commitment to the integrity of science in service to the public health continues to inspire those in the FDA and beyond.

To learn more about the life and work of Dr. Kelsey, see her "*Autobiographical Reflections*."

More about thalidomide and the 1962 Kefauver-Harris Drug Amendments that came out of this crisis can be seen at *http://www.fda.gov/Drugs/NewsEvents/ucm320924.htm*.

The FDAAA International Network Continues to Expand its Reach Globally

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. FACP

During the past year the FDAAAIN

- Met with officials of CFDA in Beijing on May 8, 2014
- Conducted GxP Training at DIA conference in Shanghai, May 11-14, 2014
- Met with Vice Minister YIN Li, MD of the CFDA at DIA China Meeting, May 12, 2014

Florence Houn MD, MPH

Zili Li, MD, MPH

FDA Fellows Program

This past year, as we have done for the past half dozen years, the FDAAA organized a seminar for the FDA Fellows on the history of FDA and current issues facing the Agency. One of the highlights of this half-day program is a panel of alumni who share their insights and wisdom. In December 2014 our panelists included Nancy Myers, Wayne Pines, Ed Steele, Bill Vodra, and Susan Winckler. In addition, FDA Historian Suzanne Junod and Steven Grossman, Deputy Executive Director of the Alliance for a Stronger FDA, made presentations. This is one of the collaborative programs that we engage in with FDA that not only educates employees at the Agency but also provides an important service to FDA.

FDAAA Scholarship Fund

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.

School of Pharmacy
TEMPLE UNIVERSITY®

2014 scholarship recipients include:

Bobby Nguyen

A first generation Vietnamese American raised in Philadelphia, Bobby Nguyen was inspired by his parents' work ethic. He financed nearly all of his college education through grants and scholarships at LaSalle University, focusing on Biotechnology/Information and Knowledge Management, which blends science and technology into an interdisciplinary field in medical science. After graduation, Mr. Nguyen worked at DuPont Performance Coatings (now Axalta Coating Systems). In his position in the Product Stewardship & Regulatory Group, he was responsible for the regulation and support of raw materials in manufacturing and R&D sites. He plans to focus on Medical Devices courses as he pursues Temple's QA/RA graduate program, so he can contribute to medical technology, providing happier and healthier lives for all.

Jeffrey Baffoe-Bonnie

Jeffrey Baffoe-Bonnie is currently a student at Temple University, planning to pursue the MS in Quality Assurance and Regulatory Affairs. He earned a BS in Biology at Pennsylvania State University from the Eberly College of Science and also minored in history. While an undergraduate, he focused on the neurobiology and pharmacological aspects of health, performing scientific research at Fox Chase Cancer Center and Penn State. Prior to this he joined a health mission team to Guatemala and studied the health of young children in Ghana. With this background he has developed a strong desire to help protect the public health with regards to medicines that they're engaged with. He is furthering his education at Temple's prominent QA/RA program to gain a deeper understanding of drug development.

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.

Lia Shields

Lia Shields graduated from Drexel University in 1999 with a BS and MS in Organic Chemistry and has worked in the pharmaceutical industry for 15 years, with one foot in the business and the other in IT. Though she has worked in pharmacovigilance, sterile manufacturing, research and development, devices, and nutrition, the main focus of her work has been systems validation and regulatory compliance. She was recently recognized as a "Quality Star" for her work supporting the validation of systems for a new manufacturing facility in Singapore. In her current position, she works from her home office in Hammonton, NJ for a multi-national pharmaceutical company's nutrition division.

Additional Scholarship Funding for Students at the FDA

In December 2014, Temple University School of Pharmacy (TUSP) in Philadelphia, PA, announced that it will fund an additional scholarship for the FDA Alumni Association (FDAAA) Centennial Scholarship each academic year. The new funding will be specifically allocated for current members of the FDA, who wish to pursue coursework in Temple's Quality Assurance and Regulatory Affairs (QA/RA) Graduate Program. The new scholarship will consist of payment for one 3-credit graduate course in the QA/RA program each year. The first scholarship will be available for the January 2015 semester and is open to any eligible candidate (For more details, see *http://www.temple.edu/pharmacy_qara/CentennialScholarship.htm*)

James Mason, CSO, Philadelphia District Office of ORA, was selected as the first recipient of the special, additional scholarship designated for current members of the FDA. James plans to begin his courses in Temple's QA/RA program in the summer 2015 or fall 2015 semester. (Currently he is traveling overseas for GMP inspections and will also be deployed to West Africa for ebola response in the spring.)

James Mason
2015 Recipient of the Special FDAAA Scholarship for FDA Personnel

James Mason is a Consumer Safety Officer (CSO) for the FDA Philadelphia District Office of Regulatory Affairs (ORA). After receiving a PharmD in 2006 from Wilkes University, he served as a pharmacy officer in the U.S. Air Force at Nellis Air Force Base in Las Vegas, NV. In 2008, he was deployed to Bagram Air Base, Afghanistan. He became a commissioned officer in the U.S. Public Health Service in 2009 and started working as a CS0 in the Philadelphia District Office of ORA. His primary responsibility consists of conducting onsite audits of pharmaceutical firms for compliance with current Good Manufacturing Practices (cGMPs). James believes that furthering his education in the QA/RA program will better enable him to support the FDA mission of promoting and protecting the public health.

FDAAA Scholarship Fund – March 2015

Temple University School of Pharmacy
QA/RA Graduate Program

Scholarships Given to Students (2014 - 2015)

From The FDAAA Endowment:	
Jeffrey Baffoe-Bonnie	2,000.00
Vishalkumar Patel	1,000.00
From the School of Pharmacy Fund:	
Lia Shields	2,000.00
Bobby Nguyen	2,000.00
James Mason (FDA)*	3,003.00
Total Given in Scholarships (2014)	$7,000.00

(*Special note: James Mason (FDA) will use his scholarship in either the summer or fall 2015 semester.)

Balance in the spendable account is currently $1,610.

Donations: April 2014 to present:	
8 Individual Donations	$2,200

Current TOTAL available in FDAAA Scholarship Fund (Feb 2014) $69,472.00

(Special note: the grand total amount of donations to the FDAAA fund to date is $54,172.60 from 56 donors. Some donors have given more than one gift.)

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*

Thank You, Dr. Hamburg

Margaret Hamburg, MD

Margaret Hamburg, MD, ended her tenure as Commissioner of Food and Drugs at the end of March 2014. During her six years as Commissioner, Dr. Hamburg was a good friend to FDAAA and demonstrated many times her understanding of the value that alumni can bring to the Agency. She participated in events sponsored by the FDAAA with obvious enthusiasm.

Alumni of the FDA often measure their service to the Agency by how many Commissioners they served. Dr. Hamburg served for six years – a long time for Commissioners in the "modern" era, and clearly served with distinction. She was outspoken in seeking funding for the FDA commensurate with its responsibilities. She lead an effort to globalize the FDA. Her emphasis on regulatory science helped advance education in this critical area. During her time in office, the reputation of the FDA was enhanced.

The members of FDAAA welcome Dr. Hamburg to the alumni ranks and to our organization, and wish her well.

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 Karen Carson
540 N St., SW, #S104
Washington, DC 20024

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.

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