



FOOD & DRUG ADMINISTRATION
ALUMNI ASSOCIATION

2019 ACHIEVEMENT HIGHLIGHTS
THE ANNUAL REPORT - 18TH EDITION

ANNUAL REPORT - 18TH EDITION





WELCOMING OUR NEW LEADERSHIP



Deb Autor
BOARD CHAIR



Allen Sayler,
PRESIDENT



MESSAGE FROM THE BOARD CHAIR

-Deb Autor

As I write this note, we are at the height of the COVID-19 crisis. This situation has changed all of our lives in many ways small and large. While we all work to care for ourselves and our families during this time, we are also reminded that FDA is working hard for all of us. We all know from personal experience how dedicated and relentless the agency is during a crisis, and we all undoubtedly have our current and former colleagues at FDA closely in our thoughts during this difficult time. This situation makes it even more important that we think carefully about how FDAAA can best achieve our goal of "Serving Those Who Served."

FDAAA serves many purposes. First and foremost, we support the agency, its mission, and its employees. As we like to say, "Once an FDAer, always an FDAer." We understand the importance and complexity of the issues that FDA faces each day, and we have the capability to support the agency, ranging from mentoring programs for FDA managers to education sessions for FDA employees to informal advice for FDA staff considering retirement. We are also here to provide moral support in difficult times, as we know from our own experience that the agency can often be misunderstood.

As an example of our support efforts, members of FDAAA were privileged to go to White Oak earlier this year during the event that FDA held to support furloughed employees. At the event, FDA senior staff provided moral support to the furloughed staff, and many FDA leaders were there to advise furloughed employees on tricky issues such as benefits and outside employment during a furlough. FDAAA members handed out candy bars and hugs to show our solidarity and support for our former colleagues. We were very well-received, and more than a few tears were shed all-around.

We hope to find ways to further support FDA during the COVID-19 crisis. We have reached out to FDA and offered our assistance. They asked us to remind all of you to please donate blood if you are able. They also thanked us for continuing to be there to support them through good times and bad.

FDAAA also serves as an important networking resource for those within the FDA and those who have left the agency who want to stay in touch with former friends and colleagues. We are known for our educational luncheons where FDA speakers share information about current issues facing the agency. We also host social events, such as the Spring and Winter Celebrations with different themes every year, where current and former friends and colleagues mix and mingle. Check out our Activities Committee Report for highlights of the year.

We also offer several other important programs. Through our International Network, FDAAA shares the FDA knowledge and expertise of its members to the agency's counterparts around the world who want to understand FDA's programs and how they operate. We also have a very active awards program that is coordinated with the FDA Honor Awards team to recognize the accomplishments of FDA staff and leaders. We even support a scholarship program for potential future FDA employees.

As we think about our work at FDAAA and launch our next phase of strategic planning, we always keep in mind how diverse we are as an organization. Membership in FDAAA is open to the thousands of FDA alumni and current employees. (Please remind current employees that they can join!) Our roster includes people who work or have worked at FDA at all levels from GS-05 employees to Commissioners. We are or have been career, political, and Commissioned Corps staff. We have experience as scientists, physicians, lawyers, biomedical engineers, administrative staff, statisticians, managers, economists, investigators, and policy makers, among others. We hail from the Office of the Commissioner, all of the product Centers, and the Office of Regulatory Affairs. Many of us are based in the DC area, but many members reside in other parts of the country and around the world. Some of our members are still actively working, while others are retired.

With that in mind, I invite you to let us know that you would like to become more active in FDAAA. There is boundless opportunity for those who want to make a difference. We welcome your ideas and your energy for bringing those ideas to life!



Before I close, I must pause to thank the many volunteers who make up FDAAA. We have many dedicated Officers, Directors, Committee Chairs and Co-Chairs, Committee Members, and Members who put in countless hours in support of FDAAA. Special thanks to Bob Brackett, Cathy Carnevale, Anne Marie Finley, and Kathy Zoon, who will be ending their FDAAA Board service (but hopefully not their FDAAA involvement) after long and illustrious tenures. Cathy and Anne Marie have both reached their three-term limit, meaning that they have served on the FDAAA Board for nine years each!

I also want to especially thank Richard Baldwin. As Chair of our Communications Committee, Richard has been working doggedly behind the scenes to create a new FDAAA web site that we hope to unveil later this year. His dedication and commitment are incredible, and we believe the fruits of his efforts will help us take FDAAA to the next level.

In closing, I want to share the moving words that then-FDA Commissioner Sharpless said about FDAAA at our annual luncheon at White Oak this year: "Because of your background and commitment and the work you continue to do, you play a very vital role in helping the FDA to be more effective in its mission to protect the American consumer." "We look to you the FDA Alumni Association and all former FDA employees who truly appreciate the role of the FDA, who understand the challenges we face and how we are working to overcome those challenges, to spread the word and make sure that people understand just why FDA is so important. Your role is not just as alumni of FDA but as alumni of public service. And by remaining active in that role you will continue to have a profound impact on the nation. Margaret Mead once wrote, 'Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it's the only thing that ever has.'":

Wishing you the best of health,

Deb Autor, FDAAA Board Chair (May 2019 – 2021)



REPORT FROM THE PRESIDENT

-Allen Sayler

The first year serving as your President has been an exciting challenge, particularly as I got to know and work together with incoming Chair Deb Autor, Co-Chair Dr. Robert Brackett, Vice President Anne Marie Finley, new and existing Board members, Committee Chairs and members and all of you dedicated current and former FDA'ers.

It was also a year of transition as the organization did some refocusing of leadership responsibilities and priorities with Deb, Anne Marie and I dividing up responsibilities for overseeing and supporting all of the FDAAA Committees. As part of that division of responsibilities, we were able to assist most committees in drafting their operational annual Plans of Action as well as submit a budget for 2020 and also set goals that can be measured over the course of 2020. This is one way to identify where we are making progress as well as to make it easier to prioritize leadership resources.

Highlights:

- Communications Committee: Hats off to Richard Baldwin and the Communications Committee for not only spearheading the effort to modernize our website, but also to improve the flow of communications throughout the entire FDAAA organization. Another notable highlight of the FDAAA Communications Committee is Alan Andersen, who almost single-handedly prepares and writes the FDAAA electronic newsletter. We anticipate an updated website becoming the focal point for FDAAA electronic communication between members and between the FDAAA leadership and members.
- Activities Committee: Under the leadership of Committee Co-Chairs Lisa Barclay and Angela Hoague, this past year resulted in a number of opportunities for FDAAA members and potential members to interact with each other, the FDA Commissioner, FDA Center Directors and leadership staff.
- Membership Services: Karen Carson continued to almost single-handedly cover all responsibilities of this committee including monitoring membership renewals, on-boarding new members, sending out and tracking FDAAA dues notices and taking care of many behind the scenes FDAAA tasks. Karen's work has been vital to the smooth functioning of FDAAA.
- Awards Committee: Howard Sklamberg and Paula Katz took over as Chair and Co-Chair of this Committee and based on their efforts to identify nominees and successfully obtain recommendations from FDAAA members as well as FDA Center Directors, demonstrated how important some new energy is in key leadership positions.
- Finance Committee: With Former FDAAA Treasurer Bryan Coleman as the new Chairman and Brian Mayhew as the incoming FDAAA Treasurer, the financial management of FDA was strengthened and modernized
- Liaison Committee: This was a work in progress to revitalize this important Committee, whose responsibility is to increase awareness and membership of FDAAA with current FDA employees. With the effort of Past FDAAA Chair Nancy Myers and the addition of Committee Chair Huong Hyunh, this Committee is starting to rebuild and again create opportunities for FDA staff to become aware of the benefits of becoming FDAAA members.
- Membership Recruitment: Led by Cathy Carnevale and Co-Chair Linda Carter, new bookmarks, pens and banners were developed to publicize FDAAA at various FDA and FDAAA-sponsored events. While Linda stepped down as Co-Chair, we are expecting exciting new membership recruitment efforts for the rest of 2020. We are also very excited to welcome Julia Luan as new Co-Chair of this Committee.
- Nominating Committee: Under the leadership of Marni Hall, the Nominating Committee is leading leadership transitions and spearheading our election process.



- International Network Committee: The International Network Committee is in the process of re-establishing its strategy for the future, with the support of Nancy Myers. We have been joined by some new members with great ideas and welcomed Co-Chair Kate Bond. FDAAA is often approached by the international community, including regulators, to provide services.

My focus and personal goals for this coming year are to continue to harness the knowledge, wisdom, experience and energy of FDAAA members in order to support the following FDAAA activities:

- Grow FDAAA membership by 10% by the end of 2020
- Establish Regional FDAAA Coordinators to act as contact points and facilitators for activities, membership recruitment and adding value to those FDAAA members living outside of Washington, DC
- Explore establishment of a FDAAA Foundation to serve as a vehicle that can receive donations from a wide variety of sources in order to support scholarship programs, FDA support services, and further the mission of both FDAAA and FDA to improve public health in the US and around the world.
- Develop a database of FDAAA members skills and expertise for use as a reference for FDAAA leadership as we explore new opportunities to interact with the Agency and other public health organizations throughout the US and internationally.

I want to encourage all of you to become involved in FDAAA, recruit your friends and professional colleagues to join FDAAA and if you have not been asked to take on a leadership responsibility, please offer as there are many things to do and ideas to explore.

Sincerely,

Allen R. Sayler

President (May 2019 – May 2020)



FDAAl International Committee (FDAAAIN)

The FDAAA International Committee has long been a crown jewel of the FDAAA; it has been active, high profile, externally focused and service oriented. In 2019, the group experienced a leadership change with Jinjie, who is stepping down as Chair. Jinjie continues to support the Committee in an interim role as leadership evolves, along with Kate Bond and Nancy Myers.

As an outcome of our efforts, FDAAIN revised its strategic plan starting in 2020.

To recap FDAAIN's current responsibilities:

International Network Committee's membership includes FDAAA members, Directors and Associate Members. The FDAAIN is responsible for:

- Engaging in regulatory capacity building of developing and emerging regulatory agencies;
- Collaborating with FDA's Office of International Programs to assist in training activities for international regulatory agencies;
- Developing and conducting training materials and activities in regulatory science targeted for regulatory agencies; and
- Receiving and disseminating international solicitations for FDAAA consultations, lectures, and training to FDAAA members interested in international activities and to the broader FDAAA membership.

As we move forward in 2020, the Committee highlighted five areas of focus for progress which are to:

1. Identify new committee leadership and identify and engage new and active members
2. Consider the creation of SOPs to ensure we maximize the impact of our current and future activities. One interesting suggestion we are exploring is how the FDAAIN could encourage the video-taping of our members' presentations and FAQs and then seeking permission to post on the FDAAA website in order to share with other interested regulators.
3. Redouble efforts to advance regulatory capacity building and while realigning our relationship with FDA's Office of International Programs, DIA China and looking for opportunities to participate in regulatory capacity building that arise in other APEC nations, Africa and Latin America
4. Explore establishment of a mentoring- type program to help new regulatory authorities implement ICH framing and documents.
5. Create a plan to engage and encourage camaraderie among current and former members of FDA's foreign offices by creating through a manageable program targeted at supporting and engaging FDAers to who are currently, formerly, and soon to be staff at the international regional offices



Jinjie Hu



Kate Bond
CO-CHAIR



Nancy Myers
LEADERSHIP ASSISTANCE



MEMBERSHIP RECRUITMENT COMMITTEE

The beginning of the year, the Membership Recruitment Committee developed goals, a plan, and a budget for the year which allowed us to stay on track. In addition to holding our scheduled committee meetings, we have:

- Developed a new letter inviting prospective members to join FDAAA, setting forth the many activities performed by the organization.
- Designed colorful bookmarks for the FDAAA, 25 of which were mailed to each FDAAA Board and Executive Board Member and the Committee chairs to hand out as they attend meetings, and educational or other events. Each bookmark, shown below, shows what FDAAA does and how to become a member.
- Purchased pens with the FDAAA logo and other promotional items to hand out to prospective members and to advertise our organization.
- Developed a portable 2' x 6' sign with a stand for use at events and to place next to a recruitment table. Our cover page for this Annual Report, includes a picture of members with the banner, so you can take a peek!
- Sent 39 email invitations to join FDAAA to persons leaving or retiring from FDA. Our FDA contact provides us with names of those persons as she learns of them.
- Mailed about 50 former FDAers invitations to join and a bookmark. This is done when other members provide us with names and addresses of people they think may like to join.
- Decided to set up and staff a recruitment table with our new sign, promotional items, as well as applications, at every FDAAA hosted event. We first did so at our Winter Celebration December 4, 2019, and it was quite a success.



Cathy Carnevale
CHAIR



Julia Luan
CO-CHAIR

FDA Alumni Association

PEOPLE-CONNECTING LEARNING TEACHING CELEBRATING SUPPORTING THE FDA!

www.FDAAA.org

JOIN NOW!



MEMBERSHIP SERVICES COMMITTEE



KAREN CARSON
CHAIR

Total Members	564
Alumni	272
Associates	42
Distinguished	14
Friends	2
Honorable	1
Lifetime	233

In 2019, the Membership Services Committee welcomed 51 members to FDAAA – 45 new members and 6 reinstated members.

Committee work is best described as ongoing or daily throughout the year.

The Committee provides specific member information to other Committees, the Board of Directors, and Executive Committee to support their work. A couple of examples:

- *a list of members in other countries (there were 6) for the Activities Committee, and*
- *the member list by state (we had members in 36 states, DC, and Puerto Rico) for the Board of Directors.*

In addition, the Committee was in almost daily contact with members updating their contact information, seeking information about dues, asking how to join FDAAA, and wanting to ensure they receive the newsletter and other announcements.



ACTIVITIES COMMITTEE



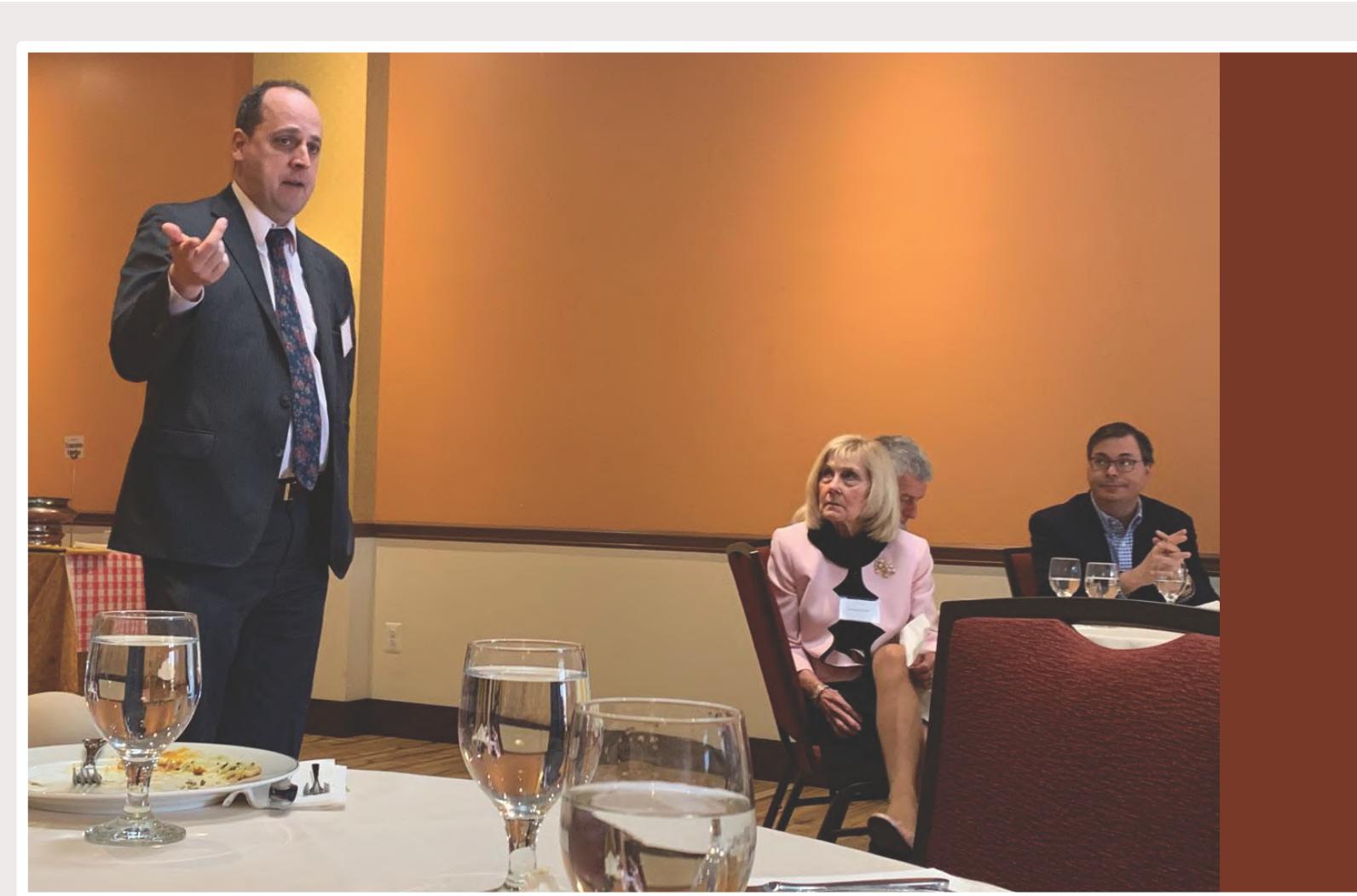
Lisa Barclay
CHAIR



ANGELA HOAGUE
CO-CHAIR



OVERVIEW OF 2019 EVENTS



Speaker Luncheon Featuring Barr Weiner- April 9, 2019

On April 9, 2019, the FDAAA Activities Committee kicked off its 2019 speaker luncheon series with guest speaker John "Barr" Weiner, J.D., Associate Director for Policy, Office of Combination Products, for a very engaging discussion about recent developments and innovative new issues in the area of combination products.

Members enjoyed the delicious Jewel of India buffet, good company, and a great presentation by Mr. Weiner, who gave a broad overview of the office's current activities and hot topics in combination products and graciously fielded lots of good questions from the audience. We are extremely grateful for Mr. Weiner's time and for his willingness to engage in such a lengthy and fruitful discussion with the group.

Summer Happy Hour in Washington, D.C. – July 18, 2019

A great time was had by all at the FDAAA Summer Happy Hour held on July 18, 2019 in downtown Washington, D.C. at MXDC. Old friends and colleagues caught up over nachos, taquitos, and delicious cold beverages. The event, which was free to all FDAAA members, provided a terrific break from the summer heat!



Fall Fling 2019 – October 1, 2019

We hosted our annual BBQ Event on the White Oak campus on October 1, 2019. The event was very well attended by current and former FDA staff. Acting Commissioner Sharpless attended, provided lengthy remarks about the current state of FDA and his support for FDAAA, and took a number of questions from the audience.



Speaker Luncheon Featuring Stacy Cline Amin – November 7, 2019

On Thursday, November 7, 2019, FDA Chief Counsel and HHS Deputy General Counsel Stacy Cline Amin was our luncheon speaker at Jewel of India restaurant near the White Oak campus. This event was well attended and extremely informative.



Winter Celebration - December 4, 2019

We hosted our Winter Celebration at Maggiano's Little Italy on December 4, 2019, and we had nearly 100 FDAAA members in attendance. Guests had a fantastic time mingling over cocktails and appetizers as we took a moment to honor the long, successful career of our friend and former FDA colleague Melinda Plaisier. Moreover, we had more generous sponsors than ever before, which will allow us to continue to host fantastic events for FDAAA members in the future.

Upcoming Events 2020

The Activities Committee was planning an ambitious line-up of events throughout 2020, including more speaker lunches, happy hours, and regional events. Unfortunately, the onset of COVID-19 has forced the Committee to postpone or cancel many of those events.

We are hopeful that we will be able to host our very popular "Fling" BBQ event in late summer or early fall, that we can pick up with our lunches and happy hours in the fall, and that we can host our Winter Celebration in late 2020. We will make details about these events available as soon as possible.



FDA ALUMNI ADVISOR PROGRAM (FDAAAAP)



Dennis Baker
COORDINATOR

The FDA Alumni Association Advisor Program's (FDAAP) mission is to assist current Agency managers in becoming more knowledgeable, skilled and effective in leadership roles. In partnership with the FDA Alumni Association and the Office of Personnel Management (OPM), FDAAAAP pairs respected retired FDA/ORA Managers (Advisors) with FDAAAAP participants, current ORA supervisors/managers (Learners), in an open, trusting and confidential mentoring relationship. The goals of this relationship are to share knowledge, experiences, organizational values, and encouragement with Learners in the continued development of management techniques, desired behavioral traits and leadership competencies.

FDAAAAP is based on the very successful, award-winning 2016 pilot program developed as a mentoring partnership between the Food and Drug Administration Office of Regulatory Affairs (ORA) and the FDA Alumni Association. Drawing on the unique expertise of the Advisors, the Learners engage in a completely individualized mentoring relationship focused on immediate and long-term developmental needs and goals.

With the assistance and guidance of OPM, this program is now expanding and there is an approved hiring of additional Annuitants to serve as Advisors. We had hoped to have the additional annuitants hired and participating in our current (Cohort 3), but due to a number of internal ORA factors the hiring of these annuitants was delayed. It is now, however, underway. Additionally, 3 of our previous annuitants resigned leaving us with a more limited set of Advisors to be paired with Learners. The Office of Training Education and Development (OTED) recently met with ORA Leadership, and efforts are underway to hire the additional annuitants to expand this highly respected program. These Advisors also serve the Potential Supervisors Program (PSP) and the Leadership Excellence Advancement Program (LEAP). When we have the information on hiring additional Annuitants, we will highlight it in the Update Newsletter.

FDAAA is very proud of this collaboration with FDA and considers this program to be a prime example of how FDA alumni and active FDA managers can work together to further the mission of the agency. Advisors have expressed great personal satisfaction from sharing their experience and knowledge as Mentors to active FDA staff.



FDAAA COMMUNICATIONS COMMITTEE



Richard Baldwin
CHAIR



COMMUNICATIONS COMMITTEE

During 2019, the Communications Committee (CC) created and shared with FDAAA Leadership, various documents to enhance association management, increase membership, and provide upgrades to the FDAAA website.

The Membership Enhancement Strategies document explored options that will appeal to the interests of FDA retirees, former FDAers, and Associates and would engage their participation.

The proposal to redesign the FDAAA website to be more attractive to alumni and associates was approved and is underway.

A Status Report on the Initiatives to Upgrade the FDAAA Website:

- Techno Goober (TG) <https://www.technogoober.com> was selected to build our new website.
 - Various meeting and T-Coms have been held with TG. Those interactions have included many committee chairs and those that would be involved in the use and maintenance of the new website.
 - A mock-up of the home page by TG has been shared with the membership.
 - As of March 2020, the new website build is at the halfway point, with an anticipated launch of June, latest July, 2020.
 - The CC Chair has sent two updates to members describing the development of the new website, various new features, and anticipated advantages to members. A third update will focus on the media available in the password protected section of the website where members can communicate with each other in various forums.

That media, within the password-protected firewall, is described as follows:

- All-Member Network Capability: The FDAAA website offers an All-Member Network that allows any dues-paying member to interact with the full membership in an informal basis.
- Social Network Capability: The FDAAA website would offer a Social Network that allows members to interact in an informal basis.
- Program Network Capability: The FDAAA website would offer a Program Network that allows for discussion among members of areas of FDA program interest and initiatives.
- Associates Network Capability: The FDAAA website would offer an Associates Network that allows for discussion among current FDA employees (Associate Members) of areas of interest to them.



Other enhancements: The new website will also feature the following:

- **E-Membership Application:** The Chair CC and Chair Members Services Committee worked together to craft an e-membership application form which contains the association's desired features. That new e-membership form was provided to TG.
- **Membership Directory:** Using our current directory as the foundation, we want the contractor to establish an easy process for members to update their information and capture additional information regarding: name, address, phone number, preferred email, interests, where the member worked at FDA, skills and expertise, which could lead into the Skill Sets Inventory described below.
- **Skill Sets Inventory and Job Listing:** Create the capability for members to post their skill sets and for other members to search for skills that match their needs.
- **FDAAA Membership Renewal and New Member Dues Process:** The Chair CC and Chair Members Services Committee worked together to create a dues payment process, which has been provided to TG.
- **FDAAA E-mail Accounts:** The situation with the current website has us using personal e-mail accounts for various purposes. TG will create "fdaaa.org" accounts.
- **FDAAA Website Content Guide:** The CC Chair has shared various documents describing our expectations with TG including an FDAAA Website Content Guide that details not only the association's expectations with TG, but also those responsibilities that will entail the FDAAA taking on the management of the new website. There will be a need for the development of Standard Operating Procedures (SOPs) specific to the roles and responsibilities of those using and managing the website.
- As noted previously, the FDAAA Website Content Guide takes the first steps in identifying FDAAA Committees that will be responsible for keeping new website current and conduct outreach
- The Chair CC will work with the Chair BoD to appropriately engage Committees via their Chairs to take responsibility for portions of the website to monitor, maintain, support, provide content, etc. The timing of this will need to be coordinated with the efforts to upgrade the website. This will also entail the development of appropriate SOPs.
- **Interim Records Retention Protocol:** The Chair, CC has previously described the need for gathering association records and our historical memory.
- At this time, the prime focus is the need to create SOPs to support the management and use of the new website. After that has been accomplished, the association can seek to find and archive other important documents, including SOPs related to the day to day business of the association.
- The archiving of paper documents will need to be handled separately.

The Upgrade of the FDAAA Website Highlights the Need to Establish Standard Operating Procedures (SOPs)

Three Draft SOPs have been created and sent to FDAAA Leadership and Committee Chairs for review.

- SOP on SOPS,
- SOP on preparing the Annual Report,
- SOP on conducting the BoD elections for vacant director positions.

As noted previously, the Chair CC will work with the Chair BoD to appropriately engage Committees via their Chairs to take responsibility for portions of the website to monitor, maintain, support, provide content, etc.

Website – Web Management SOPs, including involved Leadership and Committee Chairs:

- We will defer creating SOPs related to managing the website until we have clarity on the new website features and operations.



Communications Committee Roles and Responsibilities:

- The committee could use volunteers with IT, media, and website management expertise.

FDAAlumni Website Contact Us – The CC Chair continues to monitor this FDAAlumni e-mail account, @ mail@fdaaa.org

- The Chair of the Communications Committee is also a member of the Membership Recruitment Committee. The intent is to explore how the two committees can strategically strive for more inclusive participation by FDA retirees to join, participate, and serve in the FDAAlumni.



Group Picture Includes FDA'ers, friends, and neighbors:

Front Row: Brenda Meyer, Joselle Gatrell, Karen Carson, Connie Guerra, Marie Urban, JoAn Bosin, Pat Woodring

Second Row: Gerry Meyer, Tim Campbell, Carla Moure, Sonny Sollars, Brenda Wissler, Bill Wissler, Butch Bosin

Third Row & Up the Steps: Mary Lou Hudtloff, Marty Hudtloff, Lou Carson, Eric Sheinin, Ron Chesemore, Marine Hooten, Janet Showalter, Sue Tayman

Here's a snapshot of the mockup of the home page of our new website. Coming soon, June 2020, latest July!

Marie Urban, Richard Baldwin, Sandra Whetstone, and Betty Jones are already in a celebratory mood!

Mockup of the FDAAlumni website homepage featuring a banner for "BECOME A MEMBER TODAY!", sections for "HOW DOES A MEMBERSHIP BENEFIT YOU?", "UPCOMING EVENTS", "EVENTS CALENDAR", and "WHAT'S IN THE NEWS".

Mockup of the "OUR MISSION" section of the website, which includes a mission statement, a list of goals, and a "CLICK HERE" button.



**Allen Sayler
FDAAA PRESIDENT**

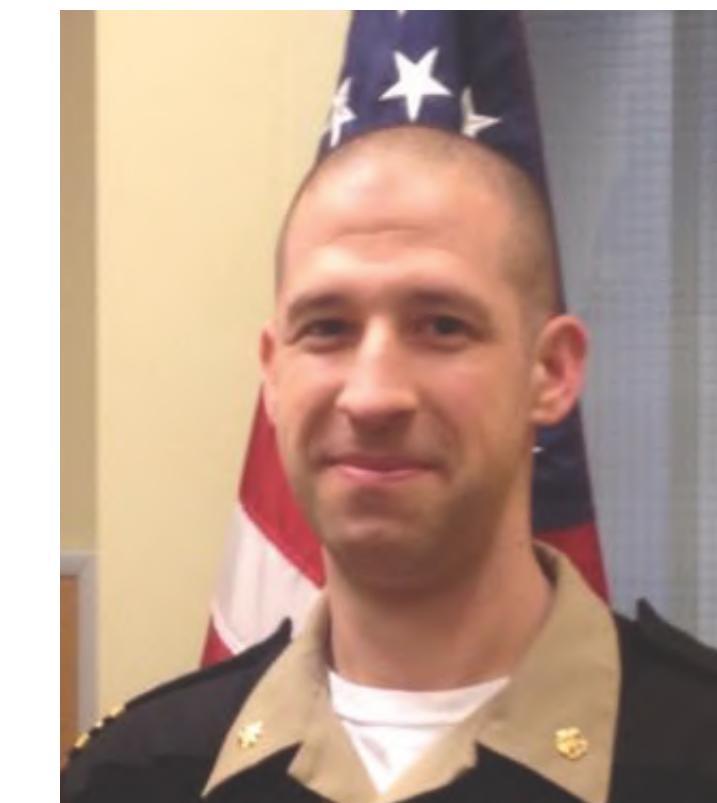
JAMES S. BENSON CENTENNIAL SCHOLARSHIP FUND

The FDAAA Temple Centennial Scholarship Fund was established to provide financial support to students at Temple University in order to advance their education in areas related to pharmacology. In June of 2018, the scholarship fund at Temple University was renamed the "James S. Benson Centennial Scholarship Fund" as a tribute to the late Jim Benson;, who was instrumental in raising the initial endowment for this fund. This FDAAA scholarship endowment fund is managed by the Temple University Board of Trustees and is self-sustaining with the financial growth each year dedicated to providing student scholarships. In 2019, two Temple University students received scholarship funds to advance their education in pharmacology, Hilda Guerrero and James Mason (see details about the award winners at the end of this report.).

The "fair market value" of the endowment as of the end of June 2019 was \$77,490.57 with \$870 contributed to the fund in the prior year. The expendable income of \$3,392.07 was committed to the two award winners. The FDAAA Executive Committee is evaluating how to re-invigorate the entire FDAAA commitment to scholarships and will be make decisions on how to incorporate the James Benson Scholarship Fund into a broader FDAAA system committed to supporting multiple scholarships.



Hilda Guerrero



James Mason

2019 James S. Benson FDA Alumni Association Centennial Scholarship Awardees

Hilda Guerrero holds a B.S. in Chemistry from Texas A&M University in Corpus Christi, Texas. She has fifteen years of combined QA and QC experience in the pharmaceutical and biopharmaceutical fields. She started her career working as a QC Research Technician at Hoechst-Celanese followed by a position at Professional Compounding Centers of America, a pharmaceutical distribution center for drugs used in compounded medicine. Currently Director of QA/RA for Baylor College of Medicine, National School of Tropical Medicine, Houston, Texas, she is responsible for GMP and FDA regulatory activities for neglected tropical disease (NTD) vaccines currently in clinical phase I/II trials in the US, Brazil and Africa. In order to comply with eCTD IND submissions, she initiated and setup the validation software system that is currently used at BCM to submit regulatory applications through the FDA ESG system. Hilda entered the RA/QA graduate program in the Fall 2016, completing the Drug Development certificate before matriculating into the MS in Spring 2018. She particularly enjoys that she can immediately apply concepts from her courses to her daily work.

James Mason received his Doctor of Pharmacy degree in 2006 and then served as an officer in the U.S. Air Force. In 2009, he was Commissioned as an officer in the U.S. Public Health Service and began working for FDA as a Field Investigator (CSO) conducting domestic and international drug GMP inspections. In 2016, he became a Pharmaceutical Specialist and now serves as a Compliance Officer for the Office of Pharmaceutical Quality Operations in Parsippany, NJ, where his primary responsibility is handling violative pharmaceutical inspections for FDA regulatory actions. He is a Board Certified Sterile Compounding Pharmacist (BCSCP) and Pharmaceutical GMP professional (ASQ CPGP).



Huong Huynh, PhD
CHAIR

ASSOCIATE MEMBER LIAISON COMMITTEE

Late 2019 saw a transition for the Associate Member Liaison Committee with new chair, Huong Huynh, Ph.D. With coordinated efforts and support from the Board, the Liaison Committee has held monthly meetings since January 2020 and developed the following mission statement. The committee members have identified four pillars on which the committee will focus to meet its mission statement.

Mission statement:

The Associate Member Committee of the FDA Alumni Association (FDAAA) serves to engage and connect current FDA employees (Associate Members) at FDA headquarters and at FDA regional offices with former FDA employees (Alumni). The Committee accomplishes this by:

- Sharing and disseminating meaningful information of mutual interest between FDA and FDAAA membership that supports our mission of serving those who have served.
- Facilitating networking activities and fostering community-building.
- Providing professional development and leadership opportunities (such as serving on committees).
- Providing a forum for exchange of ideas and strategies to develop camaraderie.



Howard R. Sklambreg
CHAIR



Paula Katz
CO-CHAIR

AWARDS COMMITTEE

The FDAAA Awards Committee has responsibility for the entire FDAAA Awards program, both internal and external to FDAAA. Many of these are presented at the FDAAA Annual Membership meeting in May. Others are presented at the FDLI Annual Meeting (typically in May) and the FDA Honor Awards Ceremony, (usually scheduled for June). As with all other aspects of FDAAA, we have faced some interesting challenges in light of the COVID-19 pandemic and, at the time of this report, we are still sorting out details about when and how all awards will be delivered to the well-deserving recipients. We are nonetheless delighted to have had a very successful "Awards Season" in 2020 with many nominations to consider in order to recognize the outstanding accomplishments and contributions of FDAAA members as well as non-members.



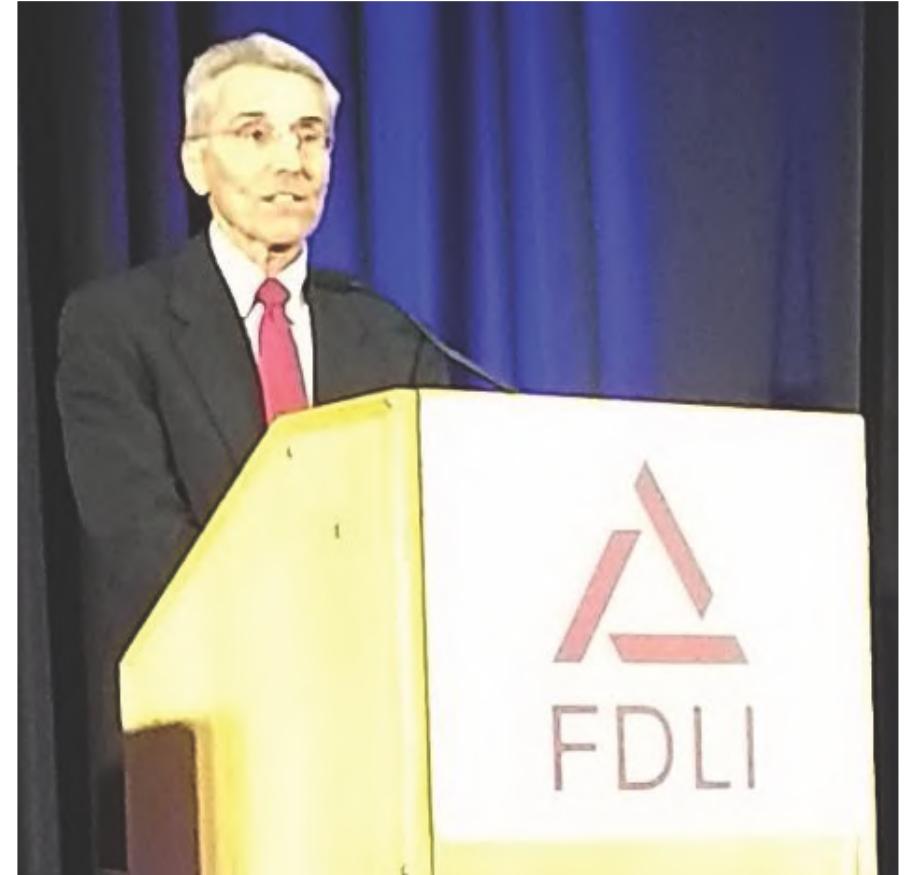
AWARDS COMMITTEE

We will provide a full list of all of the 2020 awards in our next update. Here, we wanted to share with you some of the highlights from 2019, in particular the impressive list of awards and recipients from 2019:

The FDAAA Awards Committee program underwent a number of changes during 2019-2020, with the most notable being the appointment of a new Chair (Howard Sklamberg) and Deputy Chair (Paula Katz) in August 2019, to take over from Allen Sayler, who Chaired the Awards Committee since 2017. In addition, because of a month-long federal government shutdown from late December 2018 to late January 2019, the FDA Honor Awards Ceremony was postponed until August 2019.

Based on a request from the FDAAA Executive Committee, the Awards Committee updated its strategic plan and SOP in late August 2019, which serves as the operational guide for the responsibilities and tasks for the Awards Committee on an annual basis. The new leadership of the Awards Committee and its members began the nominations solicitation task in October 2019 and provided short written reports to the Executive Committee throughout 2019. The list of successful nominees receiving FDAAA awards in 2019 is shown below.

- Distinguished Alumni Award - Mark Elengold & Norman Baylor – plaques presented at the FDA Honor Awards Ceremony at White Oak on Friday, August 2, 2019
- Harvey W. Wiley Lecture Award - Dr. Richard Pazdur, MD., Director of The FDA's Oncology Center Of Excellence (OCE) - crystal plaque presented on Friday, May 3, 2019, during the FDLI Annual Conference
- FDA Innovator Award – Theresa M Mullin, PhD, Associate Director for Strategic Initiatives, FDA Center for Drug Evaluation and Research – plaque presented at the FDA Honor Awards Ceremony at White Oak on Friday, August 2, 2019.
- John C. Villforth FDAAA Founders Award – Nancy Meyers, crystal figurine presented at the FDAAA Annual Meeting, Monday, May 13, 2019.
- Service Recognition Awards – Alan Andersen & Marie Urban, crystal figurine presented at the FDAAA Annual Meeting, Monday, May 13, 2019.
- Volunteer of the Year Awards - Lisa Barclay & Richard Baldwin, presented at the FDAAA Annual Meeting, Monday, May 13, 2019.
- Certificate of Appreciation Awards – Allen Sayler & Bryan Coleman certificates presented at the FDAAA Annual Meeting, Monday, May 13, 2019.
- Chair's Special Recognition Award - Deb Autor, plaque presented at the FDAAA Annual Meeting, Monday, May 13, 2019.
- Past Chair's Recognition Award – Nancy Meyers, crystal pitcher presented at the FDAAA Annual Meeting, Monday, May 13, 2019.
- Past President's Recognition Award -Edward Steele, cocktail set presented at the FDAAA Annual Meeting, Monday, May 13, 2019.
- Past Board Member's Recognition Award - David Chesney & Nancy Myers, wooden pen sets engraved with the FDAAA logo and name presented at the FDAAA Annual Meeting, Monday, May 13, 2019.





Food and Drug Administration Alumni Association
Serving Those Who Have Served™

THE FDAAA WISHES TO THANK DR. FAUCI

OUTSTANDING SERVICE TO SCIENCE (#THANKYOUFRFAUCI)

You might have noticed Dr. Fauci has been in the forefront of dealing with the Coronavirus Crisis and COVID-19. In 2018, The FDA Alumni Association presented our most prestigious Harvey W. Wiley award to Dr. Anthony Fauci, MD. Dr. Fauci represents the best qualities in our career federal scientists.

Our association is proud to recognize him for all that he does for every citizen in this country.

Dr. Fauci is the Director, National Institute of Allergies and Infectious Diseases, within the National Institute of Health.

The Harvey W. Wiley Award Description: A lectureship named in honor of Dr. Harvey W. Wiley, the renowned physician-chemist who, at the turn of the 20th century, championed a legislative crusade against food adulteration, earning him the title of "Father of the Pure Food and Drugs Act" when it was enacted into law in 1906.

For Dr. Fauci, the Wiley Award recommendation (by our Secretary, Marie A. Urban), has blossomed into an award well earned. Dr. Fauci continues to return even more benefits to our nation. Here's a Virtual Toast to Dr. Fauci!



Dr. Fauci



Dr. Fauci & Nancy Myers



NOMINATING COMMITTEE



**Marni Hall
CHAIR**

The Nominating Committee has the responsibility and honor of ensuring leadership roles of the FDAAA are filled. This includes identifying potential candidates and providing the Board with nominations for each Office of the Association, Committee Chairs, and open Board positions. Outreach to Alumni members for nominations to fill four Board of Director positions in the 2020 election, for the 2021- 2023 term, began in November. A final slate of six candidates was submitted to the Board in January.

The FDAAA Nominating Committee members are Norris Alderson, Kalah Auchincloss, Jennifer Devine, Ballard Graham, Betty L. Jones, Zhihong Li, Anisa Mohanty, Fatemeh Razjouyan, and Bryant Godfrey.

We will continue to engage with members to identify future candidates for all positions, to preserve robust leadership of the Alumni Association.

If you are interested in taking on a leadership role at FDAAA, let us know!



FINANCE COMMITTEE



Brian Mayhew
TREASURER



Bryan Coleman
FINANCE CHAIR

ANNUAL TREASURER'S REPORT:

It is with great pleasure that we report the sound financial standing of the FDAAA for the year ending 2019, which is a direct result of the organization's members. Without all of you, the organization is not a success. For this, the Finance Committee members want to send a heartfelt thank you to all FDAAA members.

2019 was a year of transition for the Finance Committee and, specifically, for the Treasurer role. Outgoing Treasurer Bryan Coleman moved on to Chair of the Finance Committee, while I moved into the Treasurer position. The transition brought with it the opportunity to continue the great work conducted by the Finance Committee under Mr. Coleman and the ability to enhance the processes used by the Treasurer and the Finance Committee, efforts that will continue into 2020. As further discussed in the Finance Committee Report (below), we have changes that will best serve FDAAA and its members, including:

- Consolidating the organization's banking accounts into a total of three (checking, savings and social payment service);
- Increasing total money in single savings account while establishing a maximum for balances in checking and PayPal accounts; and
- Enhancing FDAAA's use of social payment services and identify ways that the Finance Committee can work more efficiently with sibling committees.

FINANCE COMMITTEE REPORT

In 2019, outgoing Treasurer Bryan Coleman completed the transition of all Treasurer responsibilities and bank account access to the newly elected Treasurer, Brian Mayhew. Mr. Coleman agreed to serve in the capacity as Finance Chair to ensure continuity during the transition phase and as "deputy treasurer" as an alternate on all accounts for back-up.

As we transitioned the leadership role of the Finance Committee, we thank Liz Krell for her years of hard work and dedication to the Finance Committee and FDAAA, and rejoice at her continued support as committee team member.

In 2019, FDAAA continued the professional relationship with Hanztmon Wiebel (HW). However, most activities now undertaken by HW are related to Federal and State level tax filings, generation of 1099 forms and general ad hoc accounting support. The Treasurer has retained most general ledger and expense tracking and management activities.

Mr. Mayhew and Activities Committee Chair Ms. Lisa Barclay have refined the process for event sponsorship invoicing and payment tracking. Activities also continue to implement the income accounting measures derived from social activities. The Treasurer will track FDAAA income funds derived from social events and sponsorship separate from dues (working with Ms. Karen Carson) and other sources of income.

The Finance Committee, working with the Executive Committee, determined that organization only needed to maintain the General Liability Insurance coverage and have ceased efforts to rectify the outstanding issue with lapsed Non-owned and Hired Auto insurance and our Directors & Officers insurance policies which lapsed due to confusion in our communication channels with Marsh and McLennan Insurance Agency. Our Liability policy was not affected. We are currently up to date on all liability insurance policy payments.



The Finance Committee continues to support the Communications Committee on the project for website redesign and on-going maintenance contracts. As part of this effort, the Finance Committee and Membership Committee are working together in evaluating potential option beyond PayPal to be used as a means of electronic payment and funds transfer management. The potential move to a new electronic payment platform will be prioritized with other demands on the Association as it estimates what money is available for website upgrade and communications enhancement special project.

Most importantly, we want to continue to provide transparent financial information to the Executive Committee, the FDAAA Board members and FDAAA's members. To that end, we have identified below key financial information for 2019:

BANKING ACCOUNTS		
Account	Jan 1, 2019	Dec 31, 2019
Wells Fargo Checking	\$19,061.13	\$11,027.82
Wells Fargo Savings	\$44,875.60	\$45,903.10
PayPal	\$18,999.38	\$33,466.40
Capital One CD	\$10,403.03	Account Closed
Capital One Checking	\$ 3,101.97	Account Closed
Capital One Savings	\$ 1.66	Account Closed
Total	\$96,442.77	\$90,397.32

SIGNIFICANT EXPENSES		
Activity	2018	2019
Current Website Maintenance	\$8,010	\$10,214.00
Website/IT Redesign	N/A	\$1,875.00
Tax Filings/Advice	\$2,214.50	\$1,125.00
Insurance (Chubb)	\$2,422.00	\$2,422.00
SIGNIFICANT INCOME		
Activity	2018	2019
Membership Dues	\$16,790.00	\$15,480.00
Events/Activities - Net	\$20,289.00	\$ 6,183.05

As current income and expenses demonstrate, FDAAA remains in sound financial standing in 2019 and into 2020. The most significant expenses FDAAA faced in 2019 (and will continue to face in 2020) are our current website and redesigned website/IT infrastructure, which we believe will be resolved in early-to-late summer 2020. Otherwise, expenses and revenue are largely flat year-over-year. While we are planning for similar financial results in 2020, the COVID-19 pandemic may have an impact on our overall financials for 2020. The Finance Committee will monitor and report on this throughout the year.

Once again, I want to thank all FDAAA members for their continued support of the organization and we look forward to serving you in 2020.



FDAAlumni Officers

Chair, Board of Directors – Deb Autor, JD

Vice Chair – Robert Brackett, Ph.D.

President – Allen Sayler

Vice President – Ann Marie Finley

Secretary – Marie Urban

Treasurer – Brian Mayhew

General Counsel – Jessica P. O'Connell

BOARD OF DIRECTORS

Deb Autor, JD - Chair

Robert Brackett, Ph.D. – Vice Chair

Richard Baldwin

Cathy Carnevale, DVM

Lawrence Bachorik

Lisa Barclay

Ann Marie Finley, JD

Fredda Shere-Valenti

Kathy Zoon, Ph.D.

Dennis Baker

Edward Steele

Marie Urban

COMMITTEE CHAIRS

Activities Committee – Lisa Barclay and Angela Hoague

Awards Committee – Howard Sklamborg and Paula Katz

Associate Member Liaison Committee – Huong Huynh, PhD

Communications Committee – Richard Baldwin

Finance Committee – Bryan Coleman

Member Services Committee – Karen Carson

International Network Committee – Kate Bond, ScD (Co-Chair).

Member Recruitment Committee – Catherine Carnevale VMD and Julia Luan

Nominating Committee – Marni Hall