

**AFDO LEADERSHIP WORKSHOP  
PITTSBURGH, PA  
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Thomas D. Gardine  
FDA Alumni Association Member



FDA Alumni Association  
*Serving Those Who Have Served*



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FDA Alumni Association

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# What is the FDA Alumni Association?

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- **Started in early 2000's by FDA alumni**
- **Intended to serve as focal point for former employees, retirees and current employees**
- **Supports FDA and engages in activities with FDA**
- **Sponsors activities year-round to which all members are invited**
- **Brings together a special group of people who have enjoyed a similar career experience**



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## Examples of FDA Alumni Association Programs and Activities

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- **FDAAA Mentoring Programs**: using your experience to support new FDA managers
- **FDAAA Luncheon Speaker Programs** with speakers on a range of cross center topics
- **Annual Education Program** for FDA Commissioners Fellows
- **FDAAA International Network** advances foreign understanding of FDA standards and policies
- **Annual Receptions and Awards** that celebrate current and former FDAers
- **Annual Spring Fling BBQ** with the Commissioner and senior staff  
.....and More!!



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**Dr. Robert M. Califf,  
MD, FDA  
Commissioner**

*"The body of knowledge that makes an organization like FDA valuable to society resides with those who have worked there, especially in long term employees who have "seen it all," and sometimes the most useful insights come from those who can compare their FDA experiences with new jobs and roles. The **FDA Alumni Association** serves a valuable service by providing a forum where former and current FDA employees can meet not just to share common experiences but to advance FDA's mission. I am delighted that we have so many active and engaged alumni and advocate that the relationship between FDA and FDAAA continue to strengthen."*



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My Experience with

# **FDA ALUMNI ADVISOR PILOT PROGRAM**

# General Organizational Challenge

- How do you Transfer:  
    Knowledge? History? Experience?  
    As staff leave/retire
  
- How do you develop Leaders at all levels of an organization?

# FDA Alumni Advisor Pilot Program

- Collaborative effort between FDA Alumni Association (FDAAA) and Office of Regulatory Affairs (ORA)
- Purpose: to harness expertise of FDA Alumni to augment ORA leadership skills and career development
- Concept not unique, but new to FDA
- FDAAA supplied the Advisors



# FDA Alumni Advisor Pilot Program

- FDA/ORR/DHRD: Developed the Structure, Planning, Advisor Training, Administrative Support and Learners
- Pilot limited to FDA's Office of Regulatory Affairs Supervisor/Management staff.

# FDA Alumni Advisor Pilot Program

- Structured to avoid substantive regulatory or legal issues.
- Structured to avoid discussion of adverse employee actions or labor relations issues.
- Structured to focus on developing leadership competencies in Learners.

# FDA Alumni Advisor Pilot Program

- 12 FDA Alumni Association members volunteered:
  - Retired from management positions in ORA with many years FDA experience
  - All current FDAAA members
  - Advisors include former Regional Directors, HQ Office Directors, District Directors, etc.
  - Not an employee of regulated industry or a regulatory consultant
  - Received general training on mentoring others. Performed self-assessment of skills to determine areas best suited to assist Learners development.

# FDA Alumni Advisor Pilot Program

- Example FDA Alumni Advisor: Thomas Gardine
  - Over 38 years FDA experience
  - 5 years Field Investigator, ORA
  - 10 years Center Compliance Officer, CFSAN
  - 4 years Section Chief, Import Section, CFSAN
  - 7 years Division Director, Imports, ORA HQ
  - 10 years District Director, Philadelphia, ORA
  - 2 years, Deputy Regional Director, ORA

# FDA Alumni Advisor Pilot Program

- ORA Learner Selection Process
  - Targeted ORA Supervisors/Managers
  - Nominees completed self-assessment/application that details competencies wanting to improve
  - Had supervisory concurrence for program
  - Not tied to performance plan process

# Targeted Competencies for FDA Alumni Advisor Pilot Program

- Administrative Management
- Self-Management
- External Awareness
- Leveraging Diversity
- Decisiveness
- Political Savvy
- Organizational Awareness
- Professionalism
- Interpersonal Skills
- Strategic Thinking
- Developing Others
- Problem Solving
- Influencing/Negotiating
- Planning/Evaluating
- Oral Communication

# Targeted Competencies for FDA Alumni Advisor Pilot Program

- Leadership
- Vision
- Team Building
- Partnering
- Accountability
- Risk Management
- Written Communication
- Decision Making
- Conflict Management
- Customer Service
- Human Capital Management
- Integrity/Honesty

# FDA Alumni Advisor Pilot Program

- Mentoring Relationship
  - Advisors matched with ORA supervisors to discuss leadership and career development. Advisor/Learner teams are directed.
  - Relationship was developed using phone calls, webinar and emails.
  - Each participant received training and orientation documents to help set expectations.
  - Minimum of 1-6 hours a month based on competency improvement needs.



# FDA Alumni Advisor Pilot Program

- Mentoring Relationship
  - Developed Program Agreement focused upon meeting schedule and mode of communication.
  - Established Confidentiality Agreement.
  - Developed Learner Action Plan focused on competencies and goals.

# FDA Alumni Advisor Pilot Program

- Mentoring Relationship
  - Participants completed evaluation forms every 60 days and at end of pilot to assess value, quality, and efficacy of program.
  - Program started in June 2015 and concluded March 2016.

# FDA Alumni Advisor Pilot Program

## Program Status:

FDA/ORR is still assessing participant evaluations to determine the need for program improvement and viability for continuation.

# FDA Alumni Advisor Pilot Program

- Personal observations of an Alumni Advisor:
  - Pilot Strong Points:
    1. Have time to effectively Advise. When working frequently too busy to be effective.
    2. Totally dedicated to Learners needs.
    3. Only focus is how to make the Learners better.

# FDA Alumni Advisor Pilot Program

- Personal observations (cont.):
  - Pilot Potential weaknesses:
    1. Advisors who are not in pace with the times, current trends, issues, strategic focus. Need a commitment to educate ourselves on Learner “stress points”.
    2. Advisors who are too forgiving of error, too free with encouragement or praise. No “skin in the game”.

# FDA Alumni Advisor Pilot Program

- Personal Observations (cont.):
  - Great people are working for ORA.
    - Would have eagerly hired both current Learners onto my staff.
  - Role of Advisor is immensely satisfying and thoroughly enjoyable. When you have the time to do it right.
  - Wonderful to see Learners progress over time.

# FDA Alumni Advisor Pilot Program

- Questions/Answers
- Thank You