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October 24, 2013

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

I recently learned of a forthcoming conference to be held on February 6-7, 2014, intended to attract pharmaceutical industry employees and entitled "FDA Advisory Committee Prep: Real World Best Practices to Achieve Favorable Recommendations." The promotional brochure for the conference (attached *infra*) prominently urges potential attendees to **"collaborate with experts who've appeared before advisory committees and learn from current and former [FDA] advisory board members."**

A box on the first page of the brochure listing "featured industry perspectives" states that one "industry" perspective will be from Harvard Medical School. The sole Harvard-affiliated speaker is also listed on the first page as giving the "FDA advisory committee perspective," arguably suggesting that the industry perspective and the FDA advisory committee perspective may be the same. Specifically, Dr. Lynn Drake, the current chairperson of the FDA Dermatologic and Ophthalmic Drugs Advisory Committee and a lecturer at Harvard Medical School, will give a talk entitled "Pitfalls to Avoid as You Prepare for, and Present to, an Advisory Committee." The brochure touts her talk by explaining (on page 6) that attendees will **"hear directly from an FDA advisory committee chairperson about what mistakes she has seen first-hand that she wishes the sponsoring companies had avoided."**

Conference registration costs $2,199 (a "discounted" $1,899 in advance), and it is likely that Drake's presentation will be a major attraction for the pharmaceutical industry.

The decision of a current FDA advisory committee chair to serve on the faculty for this conference reflects poor judgment and seriously undermines and demeans the important FDA advisory committee process, particularly when the chair seeks to help drug companies avoid mistakes that could arguably have cost them a chance to get "favorable [advisory committee] recommendations" for their drugs. Participation in such a conference, particularly as described,

raises concerns that the advisory committee member is approaching the work of the committee from a pro-industry perspective.

Several questions thus arise:

(1) Does the FDA think it is proper for current advisory committee members to participate in such conferences?

(2) Did Drake seek advice from the FDA before agreeing to serve on the faculty for this conference? If so, what was the FDA's advice?

(3) Does the FDA have any explicit policy about current advisory committee members participating in closed-door, expensive conferences? If so, what is it? As a former member of FDA's Drug Safety and Risk Management Advisory Committee from 2008 to 2012, I do not remember reading or hearing about such a policy.

It is urgent that the FDA develop and articulate a written policy applicable to all advisory committee members to avoid repetition of this type of shameful episode, which could undermine public confidence in FDA advisory committees and in the agency itself. In Drake's case, the agency should ask her to either not participate in this conference or be removed from the FDA Dermatologic and Ophthalmic Drugs Advisory Committee.

Finally, I examined Drake's curriculum vita, as posted on the FDA's website. The CV has 32 items of information redacted. All are labeled exemption (b)(4), which reflects an FDA decision that the information represents trade secret and other confidential business information. The categories with redacted information include "Awards and Honors," with 10 deletions. I have separately made a Freedom of Information request for an unredacted copy of the CV, because the full CV may further elucidate Drake's background and relationship with the pharmaceutical industry and because the redactions seem unsupportable under FOIA. What is it about Drake that the FDA is trying to hide?

I look forward to a timely response.

Sincerely,

Sidney M. Wolfe, M.D.
Founder and Senior Adviser
Public Citizen's Health Research Group

Enclosure

REGISTER BY DECEMBER 6, 2013 AND SAVE $300!

5th Annual Summit on

FDA Advisory Committee Prep

Real-World Best Practices to Achieve Favorable Recommendations

February 6-7, 2014 • Westin Georgetown Hotel • Washington, DC

Collaborate with experts who've appeared before ad comms and learn from current and former advisory board members

KEYNOTE ADDRESS

The Role of Advisory Committees — Current Processes and Procedures

Craig Ostroff, Pharm.D., RPh,
Senior Director of Regulatory Affairs,
Otsuka Pharmaceuticals

CONFERENCE CHAIRPERSON

Steven Hamburger,
Vice President of
Regulatory Affairs,
Immunomedics, Inc.

FDA ADVISORY COMMITTEE PERSPECTIVES

Pitfalls to Avoid as You Prepare for, and Present to, an Advisory Committee

Lynn Drake, M.D., Chairperson,
FDA Dermatologic and Ophthalmic Drugs Advisory Committee;
Lecturer, **Harvard Medical School**

Learnings from the Oncology Drug Advisory Committee — A Personal Perspective

Howard Fingert, Industry Representative,
FDA Oncology Drug Advisory Committee;
Senior Medical Director, Clinical Research,
Millennium, the Takeda Oncology Company

FEATURED INDUSTRY PERSPECTIVES:

Allergan Medical • Harvard Medical School Immunomedics, Inc. • Lundbeck
Millennium, the Takeda Oncology Company • Novo Nordisk • Otsuka Pharmaceuticals
Sanofi • ThromboGenics • University of California San Francisco

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Now in its 5th year, the Summit on FDA Advisory Committee Prep brings attendees the best industry perspectives from peers who have recently appeared before FDA ad comms and offers inside insight from advisory board members.

Learn new ways to streamline processes as your company prepares to make its case for pharmaceutical product approval before an advisory committee. Walk away with strategies to successfully present before a committee and avoid potential roadblocks.

Who Should Attend:

You will benefit from attending this conference if you are an executive or senior level director from the pharmaceutical, biotech or device industries with responsibilities or involvement in the following areas:

- **Regulatory affairs**
- **Compliance**
- **Regulatory compliance**
- **Clinical operations**
- **Clinical development**
- **Clinical affairs**
- **Executive director, oncology (cardiology, dermatology, etc.)**
- **Product development**
- **Product safety**
- **Safety/risk management**
- **Medical and clinical Affairs**
- **Biostatisticians**
- **Legal/counsel**

This conference will also benefit consultants, contract research organizations and industry analysts helping to prepare sponsors for regulatory approval and advisory committee presentation.

"Prepared attendees on what to expect in an ad comm. Created awareness of what team needs to be aware of early on and not fall into a trap. Great opportunity to learn from experience of ex-chairs/panelists of earlier ad comms."

— Previous Attendee, Vipin Arora, Director of Clinical Statistics, **AbbVie**

Conference Sponsors:

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A Great Place to Meet Your Market!

Take advantage of the best opportunity to meet potential clients face-to-face. Build relationships while demonstrating thought leadership and sharing expertise. For more information on how to position your company as a sponsor or exhibitor, contact Lauren Moras at 339-298-2172 or email **lauren.moras@cbinet.com**.

DAY ONE Thursday, February 6, 2014

7:30 Conference Registration and Continental Breakfast

CHOOSE FROM TWO IN-CONFERENCE WORKSHOPS

A. Advisory Committee 101 Boot Camp

8:30 *Workshop Leaders' Welcome and Opening Remarks*

Workshop Objective:

Pharmaceutical companies that the FDA directs to appear before an advisory committee often have months, if not more than a year, of preparation work ahead of them. Let our experts help you navigate the stages of preparation as your team marches toward its advisory committee meeting. Designed for clinical and regulatory affairs professionals who are new to advisory committee preparation and proceedings, this introductory workshop takes you through the fundamentals of getting ready for an advisory committee. Walk away with practical ideas about how to set up your internal teams and build a foundation for effective preparation strategies, all of which helps you save time during planning stages.

Key Questions to Be Addressed:

- How do you create a core advisory committee team in your company that accentuates necessary skills from colleagues?
- What are successful preparation steps to take before an advisory committee meeting?
- How do you curtail pressures from executives and the advisory committee en route to a successful presentation?

Workshop Outline:

I. Create Your Advisory Committee Preparation Team
- People to include on your team, including titles, roles and colleagues you hadn't considered before
- Skills that must be represented on the team for a successful committee appearance

II. Develop and Hone Your FDA Advisory Committee Playbook
- The expected steps to take before the committee
- What to do when encountering unexpected roadblocks
- How to best prepare your presentation
- What materials to present to the advisory committee

III. Combat the Stress of Advisory Committee Meeting Preparation
- Dealing with internal pressure from executives and other stakeholders
- Project management best practices for advisory committee prep
- Defeating meeting day nerves

There will be a 30-minute networking and refreshment break at 10:00

12:00 *Close of Workshop A*

Workshop Leaders:

Elizabeth Armstrong,
Associate Director, Global Clinical Development,
Otsuka Pharmaceuticals

Ayse Baker, Director, **Sanofi**

Eric Floyd, Vice President Regulatory of Affairs and Quality Assurance, **Lundbeck**

DAY ONE Thursday, February 6, 2014

7:30 Conference Registration and Continental Breakfast

CHOOSE FROM TWO IN-CONFERENCE WORKSHOPS

B. Best Practices Seminar — Key Skills to Optimize Presentation Approaches

8:30 *Workshop Leader's Welcome and Opening Remarks*

Workshop Objective:

You've been to an FDA advisory committee meeting before and understand the essential ground rules. Now it's time to take your experiences to the next level. For people who have already appeared before an advisory committee meeting or have in-depth familiarity with them, this workshop builds upon the introductory strategies of preparation to emphasize field-tested ways to improve your chances for a favorable recommendation.

Learn how to fine-tune efforts and time spent on data that illustrates safety, efficacy and endpoint relevance while boosting presentation approaches. Also learn how to find out what issues most concern individual advisory committee panelists.

Key Questions to Be Addressed:

- What are effective strategies to demonstrate drug safety and efficacy?
- How do you best explain the benefits and limits of your research?
- How can you best use your clinical data to your advantage?
- How do you predict advisory board questions ahead of time?

Workshop Outline:

I. Get to Know Your Advisory Committee Members Ahead of Time
- Learn how to research panel members experiences and what interests them
- Predict questions from the committee roster
- Target effective ways to get your message to members before the committee meeting

II. Effectively Present Statistical and Safety Data
- Best practices to demonstrate safety thresholds
- Making statistics work for you during a presentation
- Anticipating questions about mechanism of action and proof of concept

III. Make a Compelling Scientific Argument for Drug Efficacy
- Explaining the goals, benefits and limits of your studies
- The pros and cons of which controls to use

There will be a 30-minute networking and refreshment break at 10:00

12:00 *Close of Workshop B*

Workshop Leader:

Michael Bui, D.D.S., M.P.H., J.D., Global Regulatory Strategist, Specialty Medicine – Oncology, **Bayer HealthCare Pharmaceuticals;** Industry Representative, **FDA Medical Devices Advisory Committee;** Assistant Professor of Epidemiology, School of Public Health, **Rutgers University**

Mark Senak, Senior Vice President and Partner, **FleishmanHillard**, and author of **Eye on FDA blog**

MAIN CONFERENCE

12:00 *Networking Lunch*

1:15 *Conference Chairperson's Welcome and Opening Remarks*

Steven Hamburger, Vice President of Regulatory Affairs, **Immunomedics, Inc.**

1:30 KEYNOTE ADDRESS

The Role of Advisory Committees — Current Processes and Procedures

Take an inside look at how the advisory committee process intertwines with drug submissions and why committees have taken on such an important role — and how that role is evolving. Learn how the FDA interacts with committee members, the influence the agency has on them and who else in the industry is watching your advisory committee appearances.

- Hear the latest advice on advisory committee procedures
- Learn the structure of advisory committees
- Find out what the FDA, your competitors and the press take away from committee meetings

Craig Ostroff, Pharm.D., RPh, Senior Director of Regulatory Affairs, **Otsuka Pharmaceuticals**

2:15 MOCK ADVISORY COMMITTEE

Interactive Mock FDA Advisory Committee Meeting

Experience a fully simulated mock FDA advisory committee meeting, including accurate room set-up and technology. Walk away with important lessons learned, as well as tips and techniques to address real life situations on the day of the meeting.

- Participate in the key roles of panelists, sponsor team speakers and slide identifiers
- Experience back-and-forth discussions with committee members
- Get constructive advice on your overall approach

Pete Taft, CEO and Managing Partner, **PharmApprove**

Laurie Smaldone, M.D., President, **PharmApprove**

3:45 *Networking and Refreshment Break*

4:15

Update on FDA Regulations that Affect Drug Submissions

Find out the latest information and advice about how two important regulations can affect you clinical research and how you prepare for your advisory committee appearance.

- Learn how committees use the Approved Risk Evaluation and Mitigation Strategies (REMS) to ensure drug safety
- Find out whether the U.S. Prescription Drug User Fee Act V has strengthened drug evaluations

Eric Floyd, Vice President of Regulatory Affairs and Quality Assurance, **Lundbeck**

5:00 PANEL DISCUSSION

Improve and Optimize Your Vendor Selection

Many pharmaceutical companies hire outside consulting or regulatory vendors to assist in their FDA advisory committee preparation efforts. During this panel, hear from regulatory professionals about their experiences with third-party firms and what advice they have for companies looking at vendors. Topics include:

- Determining benchmarks for vendors to meet
- What questions to ask vendors and their references
- Choosing among big versus small consulting firms
- Finding vendors who understand how the Washington, DC, regulatory environment affects your advisory committee meeting

Moderator: Pete Taft, CEO and Managing Partner, **PharmApprove**

Panelists: Stephanie DeChiaro, Senior Manager of Regulatory Affairs, **Novo Nordisk**

Fang Li, PhD, RAC, Head of Regulatory Affairs, U.S., **ThromboGenics**

5:45 *Close of Day One*

Networking, Wine and Cheese Reception
immediately following the final session on day one

DAY TWO Friday, February 7, 2014

7:30 *Continental Breakfast*

8:00 *Chairperson's Review of Day One*
Steven Hamburger, Vice President of Regulatory Affairs, **Immunomedics, Inc.**

8:15 **Determine the Final Focus of Your Presentation**

Although months of prep work are necessary and important to advisory committee success, it is also vital to have a solid understanding of what exactly the FDA and panel members want addressed in the days leading up to your meeting. Get field-tested advice to help you uncover what regulators want to know straight from a five-time veteran of advisory committee meetings.

- Find out the questions the advisory committee and the FDA want answered — ahead of time
- Incorporate your clinical trial's story into the committee's overall objectives

Diane Murphy, MBA, Director, Clinical Development Submissions, **Allergan Medical**

9:00 **Pitfalls to Avoid as You Prepare for, and Present to, an Advisory Committee**

Hear directly from an FDA advisory committee chairperson about what mistakes she has seen first-hand that she wishes the sponsoring companies had avoided. Learn steps to tackle the following problems:

- Not looking at guidance documents the FDA publishes
- Fear of talking to the FDA before your meeting
- Getting bogged down by your lawyers
- Not effectively analyzing risks up front

Lynn Drake, M.D., Chairperson, **FDA Dermatologic and Ophthalmic Drugs Advisory Committee;** *Lecturer,* **Harvard Medical School**

9:45 **How ThromboGenics Excelled During its Final Month of Advisory Committee Preparation**

Case Study

Experience the excitement, anxiety and drama from the final month of ThromboGenics's preparation prior to the company's appearance before an advisory committee, as well as the atmosphere during the actual meeting — all straight from ThromboGenics' U.S. head of regulatory affairs.

- Learn why it was important to watch the committee's morning session on another company's drug submission
- Find out how to gauge the dynamic of the advisory panel members as part of the last-minute prep for your team

Fang Li, Ph.D., RAC, Head of Regulatory Affairs, U.S., **ThromboGenics**

10:30 *Networking and Refreshment Break*

11:00 ROUNDTABLE DISCUSSION
Handling Committee Questions When You Don't Have the Data to Back Up Your Answers

In this interactive and fun exchange, break out into groups and tackle questions posed by the moderator, including the opening challenge: What would you tell an advisory committee when you don't have enough science to prove your conclusions? Share and gain insights on the following:

- Addressing problems during advisory committees
- Thinking quickly when challenged by board members
- Comparing your advisory panel approaches with those of your peers

Moderator: Steven Hamburger, Vice President of Regulatory Affairs, **Immunomedics, Inc.**

12:00 **Expert Tips To Navigate Through an Advisory Committee Meeting**

In this exclusive discussion, hear from an ex-advisory committee panelist on a variety of issues and concerns, and get tips for how to best steer through an advisory board meeting.

- Walk away with practical approaches to take during a committee meeting
- Hear real-life examples of successful strategies to keep panelists on your side
- Avoid behaviors and actions that come across negatively to committee members

Howard Maibach, M.D., Professor, Department of Dermatology, **University of California San Francisco;** *Former member of the* **FDA Dermatologic and Ophthalmic Drugs Advisory Committee**

12:45 *Networking Lunch*

1:45 **Learnings from the Oncology Drug Advisory Committee — A Personal Perspective**

The FDA's Oncology Drug Advisory Committee (ODAC) has debated several prominent submissions for new cancer-fighting treatments — and not all of those submissions met with committee approval. Hear from a current industry representative to ODAC, who gives his own personal perspectives about recent experiences and opportunities to support constructive dialogue in advisory committee sessions.

- Learn about efforts taken to broaden representation to and from the regulated pharmaceutical industry
- Find out how an industry representative to an advisory committee approaches decisions
- See what issues are important to ODAC during review of cancer drugs and predictive molecular biomarkers
- Analyze the impact of U.S. Prescription Drug User Fee Act V, Breakthrough and other accelerated mechanisms
- Review recent ODAC considerations about risk-benefit, risk mitigation, and product labeling

Howard Fingert, Industry Representative, **FDA Oncology Drug Advisory Committee;** *Senior Medical Director, Clinical Research,* **Millennium, the Takeda Oncology Company**

2:30 **CLOSING DISCUSSION**

Where Do You Go From Here? Post-Committee Actions and Follow-Up Ideas

Wrap up the conference with an informative look at the crossroads companies face after an advisory committee decision, including steps to take after an approval vote or considerations to make following a negative vote.

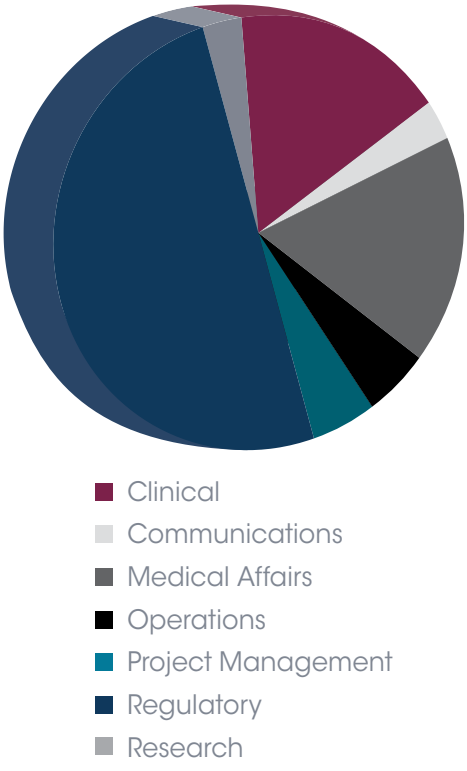
- How to continue the discussion with the FDA after a committee approval
- What the FDA wants to see next after an advisory committee vote
- Dealing with a negative vote from the committee

Diane Murphy, MBA, Director, Clinical Development Submissions, **Allergan Medical**

Lynn Drake, M.D., Chairperson, **FDA Dermatologic and Ophthalmic Drugs Advisory Committee;** *Lecturer,* **Harvard Medical School**

3:15 *Close of Conference*

Network with All Stakeholders Involved with FDA Ad Comms



"Working at a small biotech in early stage trials, this conference has added real value to our company, as we now have the opportunity to build the precepts learned into our trials as we move toward marketing approval."

— Previous attendee
Terry Chamberlin,
Director of Clinical Operations,
Genelux Corporation

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5th Annual Summit on FDA Advisory Committee Prep PC14016

REGISTRATION FEE:

	ADVANTAGE PRICING	Standard
Conference	$1899	$2199

Register by December 6, 2013 and SAVE $300. Fee includes continental breakfast, lunch, wine and cheese reception, refreshments and conference documentation. Please make checks (in U.S. funds drawn on a U.S. bank) payable to: CBI. (No personal checks accepted.)
PLEASE NOTE: All advertised discounts are taken from the final, Standard Rate.

TEAM DISCOUNT:

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SATISFACTION GUARANTEED:

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SUBSTITUTION AND CANCELLATION:

Your registration may be transferred to a member of your organization up to 24 hours in advance of the conference. Cancellations received in writing on or before 14 days prior to the start date of the event will be refunded, less a $399 administrative charge. No refunds will be made after this date; however, the registration fee less the $399 administrative charge can be credited to another CBI conference if you register within 30 days from the date of this conference to an alternative CBI conference scheduled within the next six months. In case of conference cancellation, CBI's liability is limited to refund of the conference registration fee only. CBI reserves the right to alter this program without prior notice. Please Note: Speakers and agenda are subject to change. In the event of a speaker cancellation, every effort to find a suitable replacement will be made without notice. The opinions of the conference faculty do not necessarily reflect those of the companies they represent or CBI.

VENUE:

Westin Georgetown Hotel
2350 M St. NW
Washington, DC 20037
Phone Reservations: 888-627-8406
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ACCOMMODATIONS:

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Book Now! The Westin Georgetown Hotel is accepting reservations on a space and rate availability basis. Rooms are limited, so please book early. All travel arrangements subject to availability.

CURRICULUM VITAE

NAME: Lynn Annette Drake, M.D.

ADDRESS: Harvard Medical School
Department of Dermatology
Massachusetts General Hospital
40 Blossom Street - BAR 604
Boston, MA 02114-2696
phone (617) 726-7757
fax (617) 726-1033
Email: ladrake@partners.org

(b) (4)

PRESENT TITLE: Lecturer in Dermatology
Consultant in Government and Policy
Wellman Center for Photomedicine
Department of Dermatology
Harvard Medical School

PREVIOUS TITLES

Professor and Chair
Department of Dermatology
University of Oklahoma Health Sciences Center

Deputy Chair
Department of Dermatology
Harvard Medical School

Director of Clinical Research Unit
Department of Dermaology
Harvard Medical School

Director of Government, Policy & Development
Wellman labs and Photomedicine
Cutaneous Biology Research Center
Center for Integration of Medicine and Innovative Technology
Massachusetts General Hospital, Partner's Health Care

Assistant Professor
Department of Dermatology
Emory Medical School

Chief, Dermatology Service
Veterans Medical Center
Atlanta, Ga

EDUCATION:

1963-1966	B.A., Adams State College, Alamosa, Colorado (Mathematics, Chemistry, Education)
1966-1967	M.A., Adams State College, Alamosa, Colorado (Mathematics, Education)
1968-1971	M.D., University of Tennessee School of Medicine, Memphis, Tennessee

2000-2001 A.M.P., Harvard Business School, Boston, MA.
(Advanced Management Program)

POSTDOCTORAL TRAINING:

Internship and Residencies:

1971-1972 Intern in Internal Medicine, City of Memphis Hospitals, University of Tennessee

1972-1974 Resident in Dermatology, City of Memphis Hospitals, University of Tennessee

1974-1975 Chief Resident in Dermatology, City of Memphis Hospitals, University of Tennessee

Fellowships:

1970-1971	Pediatric Student Fellow, University of Tennessee, Memphis, Tennessee
1986-1987	Robert Wood Johnson Health Policy Fellow (Congressional Fellow), Republican Leaders Office (Senator Bob Dole), Institute of Medicine, Washington, DC

LICENSURE AND CERTIFICATION:

License:

1971	Tennessee
1976	California
1980	Colorado
1981	Georgia
1988	Massachusetts
1998	Oklahoma

Board Certification:

1980	American Board of Dermatology, Diplomat
1984	American Boards of Dermatology and Pathology Special Qualification in Dermatopathology

ACADEMIC APPOINTMENTS:

1966-1967	(b) (4)
1980-1981	Instructor, Division of Dermatology, University of Tennessee, College of Medicine, Memphis, Tennessee
1981-1986	Assistant Professor of Dermatology, Emory University School of Medicine, Atlanta, Georgia
1986-1988	Health Policy Fellow, Robert Wood Johnson, U.S. Congress, Washington, D.C.
1990-1996	Assistant Professor of Dermatology, Harvard Medical School, Boston, Massachusetts
	(b) (4)
1996-2000	Professor and Chair, Department of Dermatology, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma
	(b) (4)
1998-	Lecturer on Dermatology, Harvard Medical School, Boston, Massachusetts

HOSPITAL APPOINTMENTS:

1974-1975	Chief Resident, Division of Dermatology, City of Memphis Hospitals, Memphis, Tennessee
1976-1979	Emergency Medical Group, St. Francis Hospital, Memphis, Tennessee
1979-1981	Medical Staff Member, City of Memphis Hospitals, Memphis, Tennessee.
1979-1981	Consultant in Dermatology, Federal Corrections Institute, Memphis, Tennessee.

1981-1986	Medical Staff Member, Grady Memorial Hospital, Atlanta, Georgia.
1981-1986	Medical Staff Member, Henrietta Egleston Hospital, Atlanta, Georgia.
1981-1988	Medical Staff Member, Emory Hospital, Atlanta, Georgia
1981-1988	Medical Staff Member (Partner), Emory Clinic, Atlanta, Georgia
1981-1988	Chief, Dermatology Service, Veterans Administration Medical Center, Atlanta, Georgia.
1988-	Assistant Dermatologist, Department of Dermatology, Boston, Massachusetts Massachusetts General Hospital, Boston, Massachusetts
1990-1996	Advisor on Government and Policy, Cutaneous Biology Research Center, Massachusetts General Hospital, Boston, Massachusetts
1990-1996	Director of Dermatology Clinical Investigations Unit, Massachusetts General Hospital, Boston, Massachusetts.
1997-2000	Consultant in Dermatology, Massachusetts General Hospital, Boston, Massachusetts.
2000-	Assistant in Dermatology, Massachusetts General Hospital, Boston, Massachusetts.

OTHER PROFESSIONAL POSITIONS AND MAJOR VISITING APPOINTMENTS - ACADEMIC FIELD:

National and Regional:

Appointed Positions:

1983	Consultant to FDA on Optical Radiation Hazards, Washington, DC
1984-1989	Chairman, Dermatology Field Advisory Group, Veterans Administration Central Office, Washington, DC.
1985-1989	FDA Dermatology Advisory Committee, Washington, DC
1986-1988	Robert Wood Johnson Health Policy Fellow (Congressional Fellow), Republican Leaders Office
1988	Health Advisor to George Bush for President Campaign, 1988, Domestic Policy Staff
1991	Presidential Appointment as U.S. Delegate to World Health Assembly, Geneva, Switzerland
1992-1996	National Advisory Board for Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health
1992-1997	Chairman of 1994 and 1997 Annual Meetings, American Academy of Dermatology
1994	National Policy Forum, Council on Health Care Reform
1994	Consultant, FDA Dermatology Advisory Committee
1995	Health Sciences Research Division Advisory Committee, Oak Ridge National Laboratory
1996-2000	FDA Dermatologic & Ophthalmic Drugs Advisory Committee
1997	Chairman, Annual Meeting, American Academy of Dermatology
1999-2000	Acting Chair, FDA Dermatologic & Ophthalmic Drugs Advisory Committee
2000 -	Consultant, FDA Dermatologic & Ophthalmic Drugs Advisory Committee

Senior Elected Positions:

1984-1987	President, Women's Dermatologic Society
1987-1991	Board of Directors, American Academy of Dermatology
1991-	American Dermatological Association
1995-1998	Board of Directors, American Society for Dermatologic Surgery

1995-1998	Board of Trustees, Dermatology Foundation
1997-1998	President-Elect, American Academy of Dermatology
1998-1999	President, American Academy of Dermatology
1998-	Board of Directors, Council of Nail Disorders
1999-2000	Past President, American Academy of Dermatology
2009-2013	Board of Directors, Acne & Rosacea Society

AWARDS AND HONORS:

1963-1966	Joint Honor Scholar
1963-1967	President's Scholastic Honor Society
1964-1966	Cardinal Key Honor Society
1966-1967	(b) (4)
1978-	
1980-1981	
1980-	Fellow, American Academy of Dermatology
1983-1986	(b) (4)
1984-	
1985-1986	
1986	Alumnus Outstanding Achievement Award, Adams State College
1986-1988	Robert Wood Johnson Health Policy Fellow
1986-1988	(b) (4)
1986-1987	
1988	First Annual Ralph Grover Lecturer
1988-	(b) (4)
1988	Health Advisor to George Bush for President Campaign, 1988, Domestic Policy Staff
1991	Government and Policy Advisor Award, Cutaneous Biology Research Center, Massachusetts General Hospital, Harvard Medical School
1991	Presidential Citation, American Academy of Dermatology, Guidelines of Care
1991	Presidential Appointment as U.S. Delegate to World Health Assembly, Geneva, Switzerland
1992	(b) (4)
1992	!00 Best Doctors in America
1992-1996	National Advisory Board for Arthritis, musculoskeletal and Skin Diseases of the National Institutes of Health
1994	National Policy Forum, Council on Health Care Reform
1993	Wiley Sams Memorial Lecturer
1995	Speaker Recognition Award, American College of Mohs Micrographic Surgery and Cutaneous Oncology
1996-	Who's Who in Medicine and Healthcare
1996	Duhring Lecturer, Pennsylvania Academy of Dermatology
1997	Herbert A. Luscombe Lecturer, Jefferson Medical School
1997	Outstanding Alumnus Award University of Tennessee Medical School
1997	Honorary Member, Mexican Society of Dermatology
1997-1998	AMA Leadership Forum
1998	Honorary Member, German Dermatologic Society
1998	Honorary Member, Canadian Dermatological Association.
1999	Dermatology Foundation Lecturer, Oklahoma Stte Medical Society
1999-2000	Past President, American Academy of Dermatology
2009	Honorary Membership, American Academy of Dermatology
2009	Commencement Speaker, Adams State College

MAJOR COMMITTEE ASSIGNMENTS (Other than those in professional societies):

1983	FDA Symposium on Long Term Visual Health Risks of Optical Radiation, Bethesda, Maryland
1985	New Concepts in the Non-Steroidal Therapy of Psoriasis: The Promise of New Anthralin Formulations, Invited Participant, Phoenix, Arizona
1986-	Alopecia Areata Research Foundation, Medical Advisory Board
1986-1989	FDA Dermatology Advisory Committee
1987	President's Forum: Physician Image - Malpractice Issues, Brooklodge, Augusta, Michigan
1987	President's Forum: Interrelationship Between Modern Medical Organizations - How to Improve Relations and Communications, Brooklodge, Augusta, Michigan
1988	President's Forum: A Physician's Social Responsibility, Kalamazoo, Michigan
1994	Department of Energy, Biomedical Technology Initiative
1995	FDA Ad Hoc Advisory Board on Onychomycosis
1995	Working Group Session on Health Care Quality Issues, Large States Quality Council
1995	National Policy Forum, Chairman, Task Force on Technology
1995-	Reforming Health Care Writing Group, National Policy Forum
1996-2000	FDA Dermatologic & Ophthalmic Drugs Advisory Committee
1998-	National Rosacea Foundation, Scientific Committee
1999-2000	Acting Chair, FDA Dermatologic & Ophthalmic Drugs Advisory Committee
2000-	Consultant, FDA Dermatologic & Ophthalmic Drugs Advisory Committee

Regional – Medical School

Emory Medical School:

1982-1986	Chairman, Woodruff Visiting Professors Committee
1983-1984	Dean's Ad Hoc Committee for Review of Academic Conduct
1983-1986	Woodruff Scholars Committee
1983-1986	Admissions Committee
1985-1986	Long Range Planning Committee of Radiologic Technology and Medical Imaging Programs

Regional – Hospital

Veterans Administration Medical Center - Atlanta:

1981-1986	Clinical Executive Board
1981-1984	Ambulatory Care Committee
1982-1986	Professional Standard Board
1982-1984	Medical Library Committee
1983-1986	Chairman, TAG Committee on Chemosurgery - MEDIPP Medical District 9
1983-1986	Research and Development Budget Committee
1984-1986	Housestaff Review Committee
1985-1986	Professional Standards Board

Massachusetts General Hospital:

1988-1996	Deputy Chairman, Director of Policy and Planning, Department of Dermatology
1988-1996	Executive Committee, Department of Dermatology, Harvard Medical School
1988-1996	Scientific Review Committee, Clinical Investigations Unit, Department of Dermatology
1988-1996	Director, Clinical Investigations Unit, Department of Dermatology, Harvard Medical School
1988-1996	(b) (4)
1988-1996	Chairman, Sam Moschella Teaching Scholar Committee
1989-1991	Wellman Associates Research Day
1989-1996	(b) (4)
1989-1996	Space Committee, Department of Dermatology
1989-1996	Visiting Professor Committee, Department of Dermatology
1993-1996	Subcommittee on Clinical Trials, MGH
1993-1996	Subcommittee on Human Physiology Research, MGH
1994-1996	Clinical Trials Working Group Partners (BWH/MGH) Research Task Force
1995-1996	Center for Minimally Invasive Technology (CIMIT) Working Group

University of Oklahoma Health Sciences Center:

1996-2000	Professor and Chairman, Department of Dermatology
1996-2000	Dean's Council
1996-2000	Faculty Board
1996-2000	University Physicians Medical Group Advisory Board
1997-2000	(b) (4)

MEMBERSHIPS, OFFICES, AND COMMITTEE ASSIGNMENTS IN PROFESSIONAL SOCIETIES:

American Academy of Dermatology:

1982-1985	(b) (4)
1983-1986	Chairman, Committee on Health Care and Quality Assurance
1983-1991	(b) (4)
1985-1988	Chairman, Task Force on Professional Guidelines
1986	Leadership Conference, American Academy of Dermatology
1986-1993	Council on Dermatologic Practice
1986-1995	Chairman, Committee on Guidelines of Care
1986-1995	Council on Government Affairs, Health Policy & Practice
1987-1991	Board of Directors, American Academy of Dermatology
1991-1997	Council on Scientific Assembly
1992-1993	Task Force on OSHA Blood Borne Pathogens Guidelines
1992-1993	Task Force on CLIA Guidelines
1992-1993	Task Force to Evaluate Health Care Reform Issues
1992-1993	Task Force on OSHA Biomedical Hazards Guidelines
1992-1993	(b) (4)
1993	Director, Clinical Studies Summer Session
1993-1994	(b) (4)
1995-1999	Education/Evaluation/Scientific Activities Assembly
1996-1997	Chairman, Annual Meeting, American Academy of Dermatology
1996-1997	Chairman, Council on Scientific Assembly
1996-1998	Executive Committee, American Academy of Dermatology
1996-1999	(b) (4)
1996-1999	

1997-1998	President-Elect, American Academy of Dermatology
1997-1999	Health Policy/Practice/Research Committee
1997-1999	Board of Directors, American Academy of Dermatology
1998-1999	Ex-Officio, Scientific Assembly Council
1998-1999	(b) (4)
1998-1999	President, American Academy of Dermatology
1998-1999	Ex-Offico Member of AAD Councils, Committees, Task Forces
1998-1999	AAD Chief Elected Officer, Delegate to the Council of Medical Specialty Societies
1998-1999	National Program for Dermatology for the 21st Century; Chair International Membership Study Group
1999-2000	Immediate Past President, American Academy of Dermatoloy
2005-	Academy Former Prsidents Advisory Committee
2004-2008	World Congress Fund Review Task Force

Veterans Administration Central Office:

1982-1988	Task Force on Agent Orange-Dioxin
1983-1986	Chairman, TAG Committee on Chemosurgery - MEDIPP
1985-1989	Chairman, V.A. Central Office Field Advisory Group

Women's Dermatologic Society:

1981-1984	Housestaff Liaison Committee
1981-1984	Chairman, Constitution Committee
1982-1984	Secretary/Treasurer
1983-1984	President-Elect
1985-1987	President
1987-1991	Board of Directors
1992-1996	Long-Range Planning Committee
1995-1997	(b) (4)
1996-1997	(b) (4)
2005-2008	
2004-	Past President’s Advisory Committee

Association of Professors of Dermatology:

1981-1983	Alternate Delegate to Council of Academic Societies
1985-1988	Veterans Administration Liaison Committee

Society for Investigative Dermatology:

1985-1986	Chairman, Membership Committee
1986-1988	(b) (4)
1989-	
1995	Co-Chair, Clinical Investigations Section

Dermatology Foundation:

1984-1987	Membership Subcommittee
1989-	Leaders Society, Founding Member
1995-1998	Board of Trustees

Atlanta Dermatology Society:

1982-1986	Chairman, Program Committee
1983-1985	Executive Committee
1984-1985	Ad Hoc Steering Committee for Skin Care Clinics

Georgia Dermatology Society:
1984-1985 (b) (4)

New England Dermatologic Society
1992 Chairman, Program Committee

American Society of Dermatologic Surgeons
1992-1996 (b) (4)
1995-1998 Board of Directors
2001-2005 (b) (4)

American Medical Association
1988- Practice Parameters Forum

American Dermatological Association
1998-2000 Program Committee

Council for Nail Disorders
1998-2001 Board of Director

Mexico dermatology Society
1997 Honorary Member

German Dermatological Society
1998- Honorary Member

Canadian Dermatoloy Society
1998 Honorary Member

National Rosacea Foundation:
1998- Scientific Committee
1999- Research Awards Board

Acne and Rosacea Society
2009-2013 Board of Directors

Boston Dermatologic Society
American Society of Dermatopathology - Past
American Society of Laser Medicine and Surgery - Fellow
Pacific Dermatologic Society
Oklahoma Dermatology Society - Past

Elected Memberships:
American Dermatological Association
Noah Worcester Dermatological Society

EDITORIAL BOARDS:
1983-1986 Editor of Women's Dermatologic Society Quarterly Newsletter
1984-1986 Contributing Editor of Alopecia Areata Foundation Bulletin
1986-1993 Editorial Board, Journal of the American Academy of Dermatology
1988-2005 Editorial Board, Skin and Allergy News
1994- Editor, Medical Advisor, Rosacea Review

2000- Editorial Advisory Board, Medscape Dermatology

Reviewer for: Journal of Investigative Dermatology
Journal of the American Academy of Dermatology
Archives of Dermatology
International Journal of Dermatology
Cosmetic Dermatology
New England Journal of Dermatology
Journal of Medical Association
British Journal of Dermatology
The Lancet
Journal of the American Medical Association

PUBLICATIONS: Upon Request