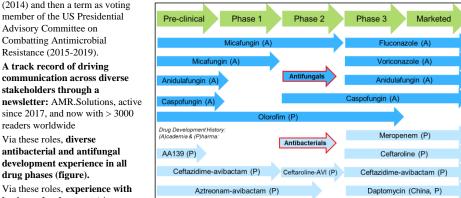
# John H. Rex, MD, FACP, FIDSA, FECMM, FFPM (Hon.) john.rex@amr.solutions

# PRESENT TITLES:

- Chief Medical Officer, F2G, Ltd., Manchester, United Kingdom
- Editor-in-Chief, AMR.Solutions
- Operating Partner, Advent Life Sciences, London, UK
- Adjunct Professor of Medicine, McGovern Medical School, Houston, TX

### **GENERAL OVERVIEW:**

- I am a science-based leader with over 35 years of experience, including:
- 15 years as an academic investigator 1987- 2002 (National Institutes of Health, Bethesda, MD; Univ. of Texas Medical School-Houston; pre-clinical translation, clinical investigator; clinical program design; US and EU regulatory interactions).
- Large pharmaceutical industry experience 2003-16 at AstraZeneca Pharmaceuticals as VP Clinical Infection (Jan 2003-May 2012) and then Senior VP and Head of Infection, Global Medicines Development (June 2012-Oct 2016).
- Small pharmaceutical industry experience at F2G Ltd (Independent Board Director then Chief Medical Officer and Director, Sep 2012-present) and Adenium Biotech ApS (Independent Board Director, Nov 2015-2019).
- Venture Capital experience both as an Operating Partner of Advent Life Science (2015-present, a VC based in London) and with multiple successful private VC-based rounds for F2G Ltd.
- Charitable foundation experience as Expert-in-Residence at Wellcome Trust (2014-2019).
- Public-Private partnership experience as co-founder of the New Drugs For Bad Bugs (ND4BB, 2012-17) within EU's Innovative Medicines Initiative (IMI), creation of DRIVE-AB (2014-2017) within ND4BB for evaluation and implementation of novel antibiotic business models, and Chief Strategy Officer for CARB-X (2016-17).
- Government advisory experience via an advisory role during creation of the US National Action Plan for AMR



drug phases (figure). Via these roles, experience with business development (six transactions while at AZ, Series E-H for F2G, Ltd).

(2014) and then a term as voting member of the US Presidential

Advisory Committee on Combatting Antimicrobial Resistance (2015-2019). A track record of driving communication across diverse stakeholders through a

readers worldwide

Via these roles, diverse

antibacterial and antifungal

development experience in all

# GLOBAL IMPACT

The hallmark of my work has been leadership via using knowledge to connect people, create new ideas, and inspire collaboration with a focus on (i) creating pathways to enable development of new antimicrobial agents, (ii) creating actual new antimicrobial agents (figure), (iii) ensuring adequate reimbursement for novel agents, and (iv) thereby ensuring access to novel agents. During my time in Industry, I have held multiple leadership roles for Industry interactions with FDA, EMA, and other external groups with a focus on enhancing available development pathways and the approaches to value for antimicrobial agents. Three particular areas of contribution have been my focus since the early 2000s:

Commented [JHR1]: ADJUST

**First,** I have had experience with regulatory interactions including **paradigm-changing work on registration pathways for novel antibacterial and antifungal agents** in settings where only limited data can be generated: Key papers include:

- Rex JH et al. Proposal for a comprehensive regulatory framework to address the unmet need for new antibacterial therapies. The Lancet Infectious Diseases 13 (3):269 275, **2013**.
- McDonnell AM, Rex JH, Goossens H, Bonten M, Fowler VG, Dane A. Efficient Delivery of Investigational Antibacterial Agents via Sustainable Clinical Trial Networks. Clinical Infectious Diseases. 2016;63 (Suppl. 2):S57-59.
- Rex, JH, et al. Progress in the fight against multidrug-resistant bacteria 2005-2016: Modern non-inferiority trial designs enable antibiotic development in advance of epidemic bacterial resistance. Clinical Infectious Diseases 65: 141-146, **2017**.
- Rex, JH, et al. Designing development programs for non-traditional antibacterial agents. Nature Communications 10: 3416, **2019.**

Second, my roles have given me **experience with changing the development and reimbursement environment for antimicrobial agents** (including a role on the US Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria). Key papers include:

- Rex JH, Outterson, K. Antibiotic Reimbursement in a Sales-Delinked Model: Context and a Benchmark-Based Global Approach. The Lancet Infectious Diseases 16:500-505, **2016**.
- Outterson K, Rex JH. Evaluating for-profit public benefit corporations as an additional structure for antibiotic development and commercialization. Translational Research, DOI: https://doi.org/10.1016/j.trsl.2020.02.006, 2020.
- Rex JH, Outterson, K. Antibacterial R&D at a crossroads: We've pushed as hard as we can ... now we need to start pulling!" Clinical Infectious Diseases <u>https://doi.org/10.1093/cid/ciaa852</u>, 2020.
- Årdal C, Balasegaram M, Laxminarayan R, McAdams D, Outterson K, Rex J, and Sumpradit N. Antibiotic development – economic, regulatory and societal challenges. Nat Rev Microbiol 18, 267–274, 2020.
- Outterson K, Orubu ESF, Rex JH, Ardal C, Zaman MH, Patient access in fourteen high-income countries to new antibacterials approved by the FDA, EMA, PMDA, or Health Canada, 2010-2020. Clin Infect Dis. 2021 Jul 12:ciab612. doi: 10.1093/cid/ciab612.
- Boucher HW, File TM, Fowler VG, Jezek A, Rex JH, Outterson K. Antibiotic Development Incentives That Reflect Societal Value of Antibiotics. Clin Infect Dis. 2021 May 4;72(9):e420-e421. doi: 10.1093/cid/ciaa092. PMID: 31999818.
- Outterson K, Rex JH. Global Pull Incentives for Better Antibacterials: The UK Leads the Way. Appl Health Econ Health Policy. 2023 May;21(3):361-364. doi: 10.1007/s40258-023-00793-w. Epub 2023 Feb 11. PMID: 36773115; PMCID: PMC10119039

**Finally, I seek to use knowledge to connect, create, and inspire through my newsletter** (<u>https://amr.solutions/</u>) and an associated YouTube channel. The newsletter currently has > 3,000 readers worldwide.

# Training and work experience (abbreviated)

- 1975-1987, Core training: Earned a BA (Rice University, Houston, Texas), an MD (Baylor College of Medicine, Houston, Texas), and completed an Internal Medicine residency (Stanford University Hospital).
- 1987-2002, Academic ID experience: Fellowship in Infectious Diseases (NIAID, NIH) and academic faculty
  appointment, culminating in a role as Professor of Medicine (University of Texas Medical School-Houston) and 5
  years of experience as the hospital epidemiologist for Memorial Hermann Hospital.
- 2003-2016 (October), Large pharma experience: A series of VP-level roles at AstraZeneca Pharmaceuticals, culminating in the sale of the AZ business unit to Pfizer.
- 2012- present, Small pharma, venture capital, charity, and public-private partnership experience: By agreement with AstraZeneca, my work during 2012-2016 (October) overlapped with a selected number of non-conflicting external roles in small pharma, a VC firm, a charity (Wellcome Trust), and a public-private partnership (CARB-X). Since the AstraZeneca-Pfizer sale, I have continued the small pharma, ventural capital, charity, and public-private partnership work begun in 2012.

# EXTENDED CV

### WORK HISTORY

2012 to present: Non-Executive (Independent) Director (2012 to 2016), then Chief Medical Officer and Director (2016 to 2021), F2G, Ltd., and Chief Medical Officer (2021 to present), F2G, Ltd.

F2G, based in Manchester in the UK, is an antifungal drug discovery and development company dedicated to finding new and clinically superior drug classes to treat life-threatening systemic fungal infections in at-risk patient populations. Currently F2G is advancing its F3 series of anti-mould compounds. This is a novel class of antifungal agent, which acts through a completely new mechanism different from all currently marketed drugs. The F3 series displays highly potent activity against clinically relevant *Aspergillus* species and many other important pathogenic moulds.

# **Responsibilities:**

- Active participation in F2G governance and strategic decisions.
- Active involvement in fund-raising and licensing, including a licensing arrangement announced 2022 with Shionogi & Co., Ltd, with an upfront of \$100m, milestones of up to \$380m, and royaltie.
- Active & direct review and guidance of compound progression via the Board's Science Committee (Sep 2012 to Oct 2016) and then as Chief Medical Officer (Nov 2016 to present).

# August 2014 to December 2019: Expert-in-Residence (EIR) and Senior Advisor for Drug-Resistant Infections, Wellcome Trust.

Based in London, UK., Wellcome Trust is one of the world's largest funders of biomedical research. As an EIR at Wellcome, I chair funding committees and serve as an advisor on their funding strategies.

# **Responsibilities:**

- o Provide advice on funding strategy and related initiatives.
- As needed, chair workshop and committees.

# November 2015 to September 2019: Non-Executive (Independent) Director, Adenium Biotech ApS.

Based in Copenhagen, Denmark, Adenium is dedicated to discovery and development of novel mechanism antibacterial therapies.

# **Responsibilities:**

- o Active participation in all Adenium Board meetings and decisions.
- o Active & direct review and guidance of compound progression via the Board's Science Committee.

# July 2016 to October 2017, Chief Strategy Officer, CARB-X.

Based at Boston University School of Law, CARB-X (www.carb-x.org) is a public-private partnership providing nonequity, non-dilutive finance in support of pre-clinical development of antibacterial products by leveraging \$250 million in US BARDA (Biomedical Advanced Research and Development Authority) funds with matching funds from the Wellcome Trust and the AMR Centre (UK).

### **Responsibilities:**

- Worked with the Executive Director to design the overall portfolio strategy for this project.
- Initiated the CARB-X<sup>ed</sup> educational initiative in collaboration with GARD-P.

### AstraZeneca (Jan 2003 to Oct 2016): An Overview

During my 14-year career at AstraZeneca, I drove a comprehensive Infection-focused and value-oriented program of teamand pipeline-building via multiple approaches to partnership, creative risk sharing, three licensing deals, three acquisitions,

and internal program progression. With these activities, the AstraZeneca Infection program progressed from having only one product in late life-cycle management in 2003 to a strongly diversified global program featuring six products in clinical development spanning all phases of clinical development, registration, and post-approval commercialization. Key events have included the 2009 registration of CUBICIN in China, the 2012 EU Marketing Authorization of ZINFORO, the 2015 approval of AVYCAZ in the United States, the 2015 co-development agreement with BARDA under its OTA (Other Transactional Authority) for ATM-AVI and a portfolio of other products, and the 2016 approval of ZAVICEFTA in the EU. This body of work concluded in November 2016 with the sale of the antibiotic business unit to Pfizer.

By agreement with AstraZeneca, my work during 2012-2016 overlapped with a selected number of non-conflicting external roles (see above).

### November 2015 to October 2016: Senior Vice President and Chief Strategy Officer, Antibiotics Business Unit, AstraZeneca

As Senior VP and Chief Strategy Officer, I reported to the Managing Director of the Antibiotics Business Unit (BU). Work in this role led to the successful sale of the AstraZeneca Antibiotics group to Pfizer during 2H16.

### **Responsibilities:**

- o Provide strategic guidance to the BU and its teams.
- o Lead business development activites for the BU.
- o Manage external policy and regulatory interactions for the BU.

# June 2012 to October 2015: Senior Vice President and Head of Infection, Global Medicines Development, AstraZeneca

As Senior VP and Head of Infection, Global Medicines Development (June 2012 to Nov 2015), I reported to the Executive Vice President of Global Medicines Development and had project, budget, and people responsibility for delivery of the Development programs supporting the AstraZeneca Infection pipeline. The role included membership in the Global Medicines Development Leadership Team, the AstraZeneca Portfolio Review Board (the body charged with governance for all late-stage programs), and the AstraZeneca Innovative Medicines Review Board (the body charged with governance for all preclinical and early-stage programs).

# **Responsibilities:**

- o Deliver the global late stage portfolio and the Life cycle management programs.
- Vision & direction for portfolio strategy for the area.
- Medical accountability for all programs in the Therapy Area.
- o Continuity of the medical view across all phases of development.
- o Continuous enhancement of people capabilities needed to support the evolving portfolio.
- o Drive the business development opportunities for the Therapy area.
- Line management responsibilities for Development staff.

### Jan 2003 through May 2012: Vice President Clinical Infection, AstraZeneca

As Vice President Clinical Infection, Oncology & Infection Therapy Area (2003-2010) and then Vice President Clinical Infection (2010-May 2012), I reported to the Global Vice President for Clinical Development. The role was a matrix-based role that included interactions with the senior AstraZeneca leadership, especially the head of the Oncology & Infection Therapy Area (2003-2010), the head of the Infection Innovative Medicines Unit (2010-2012) and the Executive Vice Presidents for Discovery, Development, and Finance (2003-2012).

# **Responsibilities:**

- o Strategic clinical leadership of anti-infective development program.
- o Management of clinical evaluation and due diligence for anti-infective licensing opportunities.
- Clinical review of discovery programs with a focus on bridging the discovery and clinical phases.
- o Oversight of clinical development program for all phases (Phase 1 to life-cycle management).
- Line management responsibility for Infection-focused physicians and clinical project leaders (growth over time from one to four independent teams comprising 19 FTE as well as ad hoc contractors and consultants).

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Commented [JR2]: September Commented [JR3]: August Commented [JR4]: February Intra- and inter-therapy area portfolio planning, priority setting, succession planning, and team building.

### Major deliverables:

- Strategic. Clinical & strategic leadership for AZ Infection as Head of Infection Disease Area Team (2003–2010).
  - <u>Developed an integrated strategy</u> for taking the Infection pipeline from a single marketed product to a
    pipeline with products in all stages of development.
  - <u>Internal champion</u> for strategy with key stakeholders including the Senior Executive Team.
  - <u>Successful collaborative delivery of strategy</u> including an investment decision to expand the physical footprint of the Discovery facility in Boston (2006), pipeline acceleration via licensing and acquisition (see below), and internal pipeline progression.
  - <u>Shaping of external environment</u> for antibiotic delivery via external interactions regarding the unmet need for antibiotics, guidelines for antibiotic development, and the need for incentives for antibiotics.
- **Development.** Delivery of the pipeline via clinical oversight of development programs:
  - Worldwide marketing program for meropenem (Merrem), including 2004-5 sNDA for complicated skin and soft-tissue infections and growth from ~\$300m/yr to nearly \$900m/yr during 2003-2010).
  - Since 2007, regular progression into first-time-in-man studies of novel antibacterial and antiviral classes based on preclinical resolution of key product challenges and understanding of relevant markers of success in early clinical programs.
  - Progression of licensed/acquired programs through key regulatory interactions (FDA, EMA, Japan PMDA, China SFDA), regulatory filings (INDs or equivalent as needed, EU scientific advice, FDA meetings), and internal investment decision milestones (decisions to invest in FTIM studies, in Phase 2b studies, and Phase 3 studies).
  - (2003-2010) As a member of the Oncology & Infection Therapy Area Portfolio Team, participation in all
    of the above-described program decisions for the Oncology portfolio with the opportunity to use challenges
    in one therapy area to inform and guide the other therapy area.
  - (2010-onward) Through support of the Clinical Development Leadership Team and the Infection Innovative Medicines unit, continued build of the people and projects supported by the Infection Therapy Area.
- **Business development.** Building the pipeline via technical leadership (and joint leadership of related business analyses) of multiple licensing reviews, including delivery of:
  - AstraZeneca-Protherics licensing deal for CytoFab (2005)
  - AstraZeneca-Cubist regional (Asia-Pacific) licensing deal for Cubicin (2006)
  - AstraZeneca acquisition of Arrow Therapeutics (2007)
  - AstraZeneca acquisition of MedImmune (2007)
  - AstraZeneca-Forest Pharmaceuticals licensing deal for Ceftaroline (2009)
  - AstraZeneca acquisition of Novexel in collaboration with Forest Pharmaceuticals (2009)

### Positions & experience prior to taking a full-time Industry role

Pharmaceutical Industry Experience and Activities as an academic investigator:

1992-2002: Academic consultant, clinical trials investigator, design of clinical development programs, and conduct of preclinical studies for fluconazole (Diflucan, Pfizer), voriconazole (Vfend, Pfizer), itraconazole (Sporanox, Janssen / Ortho-Biotech), ravuconazole (Bristol-Meyers Squibb), posaconazole (Schering-Plough), caspofungin (Cancidas, Merck), micafungin (Fujisawa), anidulafungin (Lilly / Versicor / Vicuron), amphotericin B lipid complex (ABLC, The Liposome Company / Enzon), liposomal amphotericin B (AmBisome, Fujisawa / Gilead), and liposomal nystatin (Nyotran, Aronex). Clinical trials investigator for oritavancin (Lilly / Intermune), ertapenem (Invanz, Merck), quinupristin/dalfopristin (Synercid, Aventis), levofloxacin (Levaquin, RW Johnson), linezolid (Zyvox, Pharmacia / Pfizer), and clinafloxacin (Warner-Lambert). Consultant at FDA Advisory Committees for caspofungin and voriconazole. Advisor to, and participant in, preparation of NDA and pre-NDA FDA interactions for voriconazole, caspofungin, micafungin, liposomal nystatin, and anidulafungin.

Academic Appointments:

• Jul 1992–Aug 1996: Assistant Professor of Medicine, University of Texas Medical School at Houston

**Commented [JHR5]: Internal recognitions.** Team Leader of Due Diligence team that won 2004 "Mission, Vision, and Values" award for timely delivery of a complex (3-way) product opportunity review. Merrem marketing & development team won 2004 "Drive the Curve" award for sustained product growth. Merrem development team won 2005 "Collaborate as One Team" award for timely delivery of Merrem NDA.

- Apr 1994–Aug 1996: Assistant Professor of Medicine, University of Texas M. D. Anderson Cancer Center
- Sep 1996–Aug 2001: Associate Professor of Medicine, University of Texas Medical School at Houston
- Sep 2001–Dec 2002: Professor of Medicine, University of Texas Medical School at Houston
- Jan 2003 to present: Adjunct Professor of Medicine, McGovern Medical School, Houston, Tx

# Hospital Appointments:

- Jul 1992–Dec 2002: Medical Staff, Hermann Hospital
- Jul 1992-Dec 2002: Medical Staff, Harris County Hospital District
- Aug 1997–Dec 2002: Medical Director for Epidemiology, Hermann Hospital

### EDITORIAL BOARDS, EDITORSHIPS, ADVISORY BOARDS, AND COMMITTEES:

#### Editorial Boards (current roles shown in bold) 1994-2000 Editorial Board, Antimicrobial Agents and Chemotherapy 1996-2001 Editorial Board, Diagnostic Microbiology and Infectious Disease Commented [JHR7]: Actual stop date unknown - five years 1997-present presumed but cannot be verified as journal lacks adequate details Editorial Board, Drug Resistance Updates 1997-2020 Editorial Board, European Journal of Clinical Microbiology & Infectious Diseases Commented [JHR8]: DRU still active on 26 Jan 2025 1999-2002 Editorial Board, Current Opinion in Anti-infective Investigational Drugs Commented [JHR9]: Stop date uncertain: last verified 2019 so 2001-2004 Editorial Board, MD Consult (www.mdconsult.com) using 2020. Noted that I was not on the editorial board in 2023. 2003-2010 Highlights Advisory Board, Nature Reviews Microbiology Commented [JHR10]: Actual stop date unknown - three years 2020-present Editorial Advisory Board, Clinical Infectious Diseases presumed but cannot be verified as online materials lack adequate details. MDconsult was closed down in 2014. Editorships (current roles shown in bold) Commented [JR11]: Actual stop date unknown. Last verified 1994-1998 Associate Editor, Medical Mycology (formerly Journal of Medical and Veterinary Mycology) Feb 2010. 2000-2002 Co-Editor-in-Chief and Founder, www.doctorfungus.org, a non-profit web site devoted to Commented [JR12]: Invited to join 6 Dec 2019, presume active dissemination of information about medical mycology from Jan 2020. Still active as of 26 Jan 2025 2000-2010 Editor, Antimicrobial Agents & Chemotherapy (term ended 30 June 2010) 2003-2006 Section Editor for Anti-Infectives, Current Opinion in Anti-infective Investigational Drugs Emeritus Editor, www.doctorfungus.org. 2003-present Advisory Boards: 1999-2002: Voriconazole Global Advisory Board, Pfizer Pharmaceuticals 1999-2002: Caspofungin Advisory Board (chairman), Merck Research Laboratories 1999-2001: Nyotran Advisory Board, Aronex Pharmaceuticals and Abbott Laboratories 2000-2002: AmBisome Scientific Advisory Board, Gilead Sciences, Inc. Anidulafungin Scientific Advisory Board, Versicor, Inc. 2000-2002. 2001-2003: Consultant to the Microbiology Devices Panel of the Medical Devices Advisory Committee, Center for Devices and Radiological Health, Food and Drug Administration 2001-2002: Infection Therapy Area Management Board, AstraZeneca Pharmaceuticals National and International Committees (current roles shown in bold) 1993-2002 Member, Antifungal Susceptibility Testing Subcommittee, National Committee for Clinical Laboratory Standards Commented [JHR13]: 1994-2000 Chair, Working Member, Program Committee for ICAAC, the annual Interscience Conference on Antimicrobial Group on Detection of Amphotericin B Resistance, Antifungal Susceptibility Testing Subcommittee, National 1997-2002 Agents & Chemotherapy sponsored by the American Society for Microbiology Committee for Clinical Laboratory Standards 2000-2002 Vice-President, International Society for Human and Animal Mycology (ISHAM) Commented [JHR14]: 2001-2002 Member, Program 2001-2008 Member, Program Committee for ACAR, the Annual Conference on Antimicrobial Resistance Committee for the John E. Bennett Forum on Deep Mycoses sponsored by the National Foundation for Infectious Diseases (NFID) Study Design 2003-2008 Chair, Antifungal Susceptibility Testing Subcommittee, Clinical Laboratory Standards Institutes (CLSI, formerly National Committee for Clinical Laboratory Standards [NCCLS]) Corresponding Member, Program Committee for 16th European Congress of Clinical Microbiology 2005-2006 and Infectious Diseases (ECCMID 2006, Nice, Italy), sponsored by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) 2005-2008 Member, Program Committee Infectious Diseases Society of America annual meeting 2006 Advisor, Area Committee on Microbiology, Clinical Laboratory Standards Institutes (CLSI, formerly National Committee for Clinical Laboratory Standards [NCCLS])

**Commented [JHR6]:** September 2021: Extended another year per correspondence with Dr. Colasurdo (President of UTHSC), see copy of correspondence in folder with CV.

2006-2007	Member, Program Committee for 17th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2007, Munich, Germany), sponsored by the European Society of Clinical
	Microbiology and Infectious Diseases (ESCMID)
2006-2009	Advisor, M23 Working Group, Clinical Laboratory Standards Institutes (CLSI, formerly National
	Committee for Clinical Laboratory Standards [NCCLS])
2007	Voting Member, Area Committee on Microbiology, Clinical Laboratory Standards Institutes (CLSI, formerly National Committee for Clinical Laboratory Standards [NCCLS])
2007	Consultant to CDC Task Force on <i>Update of A Public Health Action Plan to Combat Antimicrobial</i>
2007	Resistance. Public Meeting December 12-13, 2007
2007-2011	FDA CDER Anti-Infective Drug Advisory Committee, Industry Representative (term ran 1 Nov 07 to
2007-2011	31 Oct 2011)
2008	Vice-Chair, Area Committee on Microbiology, Clinical Laboratory Standards Institutes (CLSI,
2000	formerly National Committee for Clinical Laboratory Standards [NCCLS])
2009-2012	Chair, Consensus Committee on Microbiology, Clinical Laboratory Standards Institutes (CLSI,
	formerly National Committee for Clinical Laboratory Standards [NCCLS])
2009-present	Advisor, Antifungal Susceptibility Testing Subcommittee, Clinical Laboratory Standards
•	Institute (formerly National Committee for Clinical Laboratory Standards)
2009-2012	Member, Research on Resistance Working Group, Infectious Diseases Society of America
2009-2013	Chair, European Federation of Pharmaceutical Industries and Associations (EFPIA) Antimicrobial
	Working Group
2010-2011	Abstract Review Committee, European Congress of Clinical Microbiology and Infectious Diseases,
	Milan, Italy.
2010-2012	Member, FDA-sponsored Foundations for the NIH working group on Endpoints for Clinical Trials in
	Community-Acquired Bacterial Pneumonia and Skin Infections
2011-2012	Abstract Review Committee, European Congress of Clinical Microbiology and Infectious Diseases,
	London, United Kingdom
2011-2015	Member and Chair, Wellcome Trust "Seeding Drug Discovery" Funding Committee
Multiple dates	Member, PhRMA Antimicrobial Resistance working groups and Limited Duration Key Issues Teams
2012 2015	(LD-KITs)
2012-2015	Member, Brookings Council on Antimicrobial Drug Development
2012-2013	Abstract Review Cmte, European Congress of Clinical Microbiology and Infectious Diseases
2012-2018	Member, FDA-sponsored Foundations for the NIH working group on Endpoints for Clinical Trials in
2012 2016	Hospital-Associated and Ventilator-Associated Pneumonia
2013-2016 2013-2016	Vice Chair, Consensus Committee on Microbiology, Clinical Laboratory Standards Institute Member, Nominating Committee, Clinical Laboratory Standards Institutes
2013-2010	Advisor to PCAST, the President's Council of Advisors on Science and Technology
2014 2015	Member, Organizing Committee for 26-27 Mar 2015 IOM (Institute of Medicine) workshop entitled:
2015	Enabling Rapid Response with Medical Countermeasures to Mitigate Risk of Emerging Infectious
	Diseases: An Institute of Medicine Workshop.
2017	Program committee, 2017 ESCMID/ASM Conference on Drug Development to Meet the Challenge of
2017	Antimicrobial Resistance
2015-2019	Voting Member, US Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
	(PACCARB)
2018-2021	Program committee, ESCMID/ASM Conference on Drug Development to Meet the Challenge of
	Antimicrobial Resistance
2018-2021	Chair, Novo REPAIR Impact Fund Scientific Advisory Board
2021-present	Chair, AMR Action Fund Scientific Advisory Board

# TRAINING:

Advanced Training Courses:

 Recombinant DNA Methodology (18 lecture hours, 20 laboratory hours), June, 1990, Foundation for Advanced Education in the Sciences, National Institutes of Health, Bethesda, MD. **Commented [JR15]:** This date is very approximate – there was no official end — I've chosen 2013 as one year after the last truly EFPIA-based workshop with EMA (2012-10-25, 26 EMA addendum workshop). I suppose you could argue for the 2014 PK-PD workshop, but this was really IFPMA-based.

- Special Topics and Methods in Recombinant DNA Research (18 lecture hours, 20 laboratory hours), July, 1990, Foundation for Advanced Education in the Sciences, National Institutes of Health, Bethesda, MD.
- Statistics for Biomedical Scientists I (6 credits), Fall 1988–Spring 1989, Foundation for Advanced Education in the Sciences, National Institutes of Health, Bethesda, MD.
- Symposium on Techniques in Patient-Oriented Research (18 lecture hours), October 30–November 1, 1992.
   Sponsored by the University of Texas Southwestern Medical Center at Dallas and the GCRC Program of the National Center for Research Resources, National Institutes of Health.
- Training Course in Hospital Epidemiology (23 lecture hours), October 25-28, 1997. Sponsored by Society for Healthcare Epidemiology of American and Center for Disease Control and Prevention (SHEA/CDC).
- Finance for Directors and Senior Executives, September 15-16, 2008. Helmsley Fraser, London.

### Postgraduate Training:

- August 1982 to September 1983: Henry Luce Scholar in Seoul, Korea.
- September 1983 to June 1984: Clinical Associate, Section of Infectious Diseases, The Methodist Hospital, Baylor College of Medicine, Houston, Texas
- July 1984 to June 1987: Resident in Internal Medicine, Stanford University Hospital, Stanford, California
- July 1987 to June 1992: Medical Staff Fellow, Clinical Mycology Section, Laboratory of Clinical Investigation, National Institute of Allergy and Infectious Diseases, Bethesda, Maryland

### Graduate Education:

• August, 1982 — M.D., with Honors, Baylor College of Medicine, Houston, Texas

Undergraduate Education:

• June, 1979 — B.A., summa cum laude, Phi Beta Kappa, Rice University, Houston, Texas

### LICENSURE, CERTIFICATIONS, HONORS AND AWARDS, PROFESSIONAL ORGANIZATIONS:

### Licensure:

• Texas State Board of Medical Examiners, License No. G8957, licensed December, 1985

### Certification:

- American Board of Internal Medicine, 1987, Time-Unlimited Certificate Number 115189.
- American Board of Internal Medicine (Infectious Diseases), 1990-2000, Time-Limited Certificate Number 115189. Recertified May 2000 for 2000-2010. Recertified October 2009 for 2010-2020.

# Honors and Awards

- Phi Beta Kappa
- Alpha Omega Alpha
- Dean's Excellence Award, University of Texas Medical School-Houston, 1996
- Outstanding Achievement in Clinical Service, University of Texas Medical School-Houston, 1996
- Fellow, American College of Physicians (ACP), 1997
- 1999 Quality Team of the Year for Financial Improvement, Memorial Hermann Health Care System
- Memorial Hermann Hospital Physician of the Year, 2001
- Best Doctors in America, Infectious Diseases, 2002–04
- Excellence in Standards Development, Clinical & Laboratory Standards Institute, 2006
- Fellow, Infectious Diseases Society of America (IDSA), 2006
- Fellow, European College of Medical Mycology, 2016
- Fellow, Faculty of Pharmaceutical Medicine (FPM), Honorary, 2024

### Professional Organizations:

- Infectious Diseases Society of America
- American Society for Microbiology
- · International Society for Human and Animal Mycology
- American College of Physicians

# FELLOWS TRAINED

David M. Cohen, M.D. (1992-1995), Marcelo Martins, M.D. (1993-1997), Monica Grazziutti, M.D. (1994-1997), Libsen Rodriguez, M.D. (1995-1998), Mario Lozano-Chiu, Ph.D. (1995-1999), Sevtap Arikan, MD. (1997-1998), Liang Xia, MD (1998-2000), Luis Ostrosky-Zeicher, MD (1999-2002), Banu Sancak, MD (2000-2001), Niki Paphitou, MD (2000-2002), Madonna Matar, MD (2001-2002), Roberto Andrade, MD (2001-2002),

# PUBLICATIONS

Summary: Original Articles (129); Reviews, Editorials, and Invited Papers (54); Consensus Development, Guideline, and Policy Papers (42); Group Authorship (3); Book Chapters (63); Abstracts (151); Major Presentations at National and International Meetings (169)

# A. Original Articles (in red when journal impact factor is 10+)

- Rex JH, Harris RL, Wheeler T, White M, Bradshaw M, Williams TW. Granulomatous disease complicating hairy cell leukemia. Tex Med 81:31-3, 1985.
- Harris RL, Lawrie GM, Wheeler TM, Rex JH, Sarosi GA, Jacob MC, Bradshaw MW, Williams TW. Successful management of *Histoplasma capsulatum* infection of an abdominal aortic aneurysm. J Vasc Surg 3:649-51, 1986.
- 3. Rex JH, Ginsberg AM, Fries LF, Pass HI, Kwon-Chung KJ. *Cunninghamella bertholletiae* infection associated with deferoxamine therapy: A case report and review of the literature. Rev Infect Dis 10:1187-94, 1988.
- 4. Rex JH, Bennett JE, Gallin JI, Malech HL, Melnick DA. Normal and deficient neutrophils can cooperate to damage *Aspergillus fumigatus* hyphae. J Infect Dis 162:523-528, 1990.
- 5. Rex JH, Bennett JE. Administration of potassium iodide to normal volunteers does not increase killing of *Sporothrix schenckii* by their neutrophils or monocytes. J Med Vet Mycol 28:185-9, 1990.
- Rex JH, Bennett JE, Gallin JI, Malech HL, DeCarlo ES, Melnick DA. In vivo interferon-gamma therapy augments the in vitro ability of chronic granulomatous disease neutrophils to damage *Aspergillus* hyphae. J Infect Dis 163:849-52, 1991.
- 7. Rex JH, Hanson LH, Amantea MA, Stevens DA, Bennett JE. Standardization of a fluconazole bioassay and correlation with results obtained by high-pressure liquid chromatography. Antimicrob Agents Chemother 35:846-50, 1991.
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# Commented [JHR16]: Awards to Fellows-in-Training

1993: David Cohen received an honorable mention in the Annual M. D. Anderson Research Fellow Paper Competition 1994: Marcelo Martins received first place in the annual Texas Infectious Diseases Society Research Fellow Paper Competition 1995: Mario Lozano-Chiu received a Postdoctoral Research Award from the Sociedad Española de Quimioterapia to support his travel and first year of research 1996: Mario Lozano-Chiu received an award from the Ministerio de Educación y Ciencia de España to support his travel and second year of research 2000: Luis Ostrosky-Zeichner received a George McCracken ID Fellow Travel Grant for the 40<sup>th</sup> ICAAC in Toronto, Ontario 2001: Luis Ostrosky-Zeichner received a George McCracken ID Fellow Travel Grant for the 41st ICAAC in Chicago, Illinois Niki Paphitou received a George McCracken ID Fellow 2001: Travel Grant for the 41<sup>st</sup> ICAAC in Chicago, Illinois 2002: Roberto Andrade received a George McCracken ID Fellow Travel Grant for the 42<sup>st</sup> ICAAC in San Diego, CA 2002: Niki Paphitou received a George McCracken ID Fellow Travel Grant for the 42<sup>nd</sup> ICAAC in San Diego, CA 2002: Madonna Matar received a George McCracken ID Fellow Travel Grant for the 42nd ICAAC in San Diego, CA

**Commented [Rex17]:** Be sure to update LinkedIn as well when the totals change.

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- 111. Ostrosky-Zeichner L, Rex JH, Paetznick VL, Rodriguez JR, Chen E, Pappas PG, Dismukes WE. Lack of correlation of in vitro checkerboard-based antifungal combination results with clinical outcomes. 44<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Abstract M1679, 2004.
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- 113. Oude Lashof AML, Sobel JD, Ruhnke M, Pappas PG, Viscoli C, Schlamm HT, Rex JH, Kullberg BJ. Safety and tolerability of voriconazole compared to amphotericin B followed by fluconazole in patients with candidaemia and baseline renal insufficiency. 14<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases, Munich, Germany, Abstract P977, 2007.
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Triazoles Using Clinical and Laboratory Standards Institute (CLSI) Method. 49<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Abstract M-1716/485, 2009.

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- 117. Hope W, McEntee L, Johnson A, Farrington N, Whalley S, Santoyo-Castelazo A, Birch M, Law D, Kennedy T, Heep M, Rex J. Pharmacodynamics of F901318 against Aspergillus fumigatus in a rabbit model of invasive pulmonary aspergillosis (IPA). 27<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases, Vienna, Austria, 22–25 April, 2017
- 118. Lakota EA, Bulik CC, Bader JC, Bhavnani SM, Dale GE, Wallnoefer A, Rex JH, Ambrose PG. Mind the Gap: A Pharmacokinetic-Pharmacodynamic (PK-PD) Evaluation of Ertapenem for Patients with Ventilator-Associated Bacterial Pneumonia (VABP). ASM Microbe, New Orleans, 1-5 June 2017 (3 June 2017 abstract, session 264).
- 119. Seyedmousavia S, Chang Y, Law D, Birch M, Rex JH, Kwon-Chung KJ. Efficacy of dihydroorotate dehydrogenase inhibitor F901318 against invasive aspergillosis due to *Aspergillus funigatus*, *A. nidulans* and *A. tanneri* in profoundly neutropenic and chronic granulomatous disease murine models. 8<sup>th</sup> Advances Against Aspergillosis, Lisbon, Portugal, 1-3 Feb 2018 (submitted abstract).
- 120. Talbot GH, Das A, Torres A, Powers JH, Cush S, Dane A, Wible M, Echols R, Cammarata S, Rex JH, Fleming T, and Hoffmann S for the Biomarkers Consortium (BC) of the Foundation for the National Institutes of Health (FNIH) HABP/VABP Project Team. Alternatives to the All-cause Mortality (ACM) Endpoint for the Study of Hospital-Acquired Bacterial Pneumonia(HABP) and Ventilator-Associated Bacterial Pneumonia (VABP). 28<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases, Madrid, Spain, 20-25 April 2018, Abstract #3570.
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- 123. Wiederhold NP, Patterson H, Birch M, Law D, Rex JH. Evaluation of the In vitro Activity of Olorofim Against *Fusarium* Species. 9th Trends in Medical Mycology (TIMM-9), 11-14 October 2019, Nice, France (abstract).
- 124. Seyedmousavi S, Chang Y, Law D, Birch M, Rex JH, Kwon-Chung KJ. In vivo efficacy of olorofim against systemic infection caused by *Scedosporium apiospermum, Pseudallescheria boydii*, and *Lomentospora prolificans* in neutropenic CD-1 mice. 9th Trends in Medical Mycology (TIMM-9), 11-14 October 2019, Nice, France (abstract).
- 125. Buil JB, Oliver JD, Law L, Tehupeiory-Kooreman M, Rex JH, Hokken MWJ, Melchers WJG, Birch M, Verweij PE. Molecular mechanism and frequency of olorofim resistance in *Aspergillus fumigatus*. 9th Trends in Medical Mycology (TIMM-9), 11-14 October 2019, Nice, France (abstract).
- 126. Buil JB, Oliver JD, Birch M, Law L, Rex JH, Tehupeiory-Kooreman M, van de Lee HAL, Melchers WJG, Verweij PE. In vitro susceptibility of olorofim against 1,682 clinical *Aspergillus* isolates. 9th Trends in Medical Mycology (TIMM-9), 11-14 October 2019, Nice, France (abstract).
- 127. Buil JB, Oliver JD, Law L, Tehupeiory-Kooreman Rex JH, Hokken MWJ, Melchers WJG, Birch M, Verweij PE. Molecular mechanism and frequency of olorofim resistance in *Aspergillus fumigatus*. 9th Trends in Medical Mycology (TIMM-9), 11-14 October 2019, Nice, France (submitted abstract).
- 128. Chen S, RaiL NJ, Cunneen S, Cornelissen K, Rex J, Chris Heath C. A case of *Lomentospora prolificans* (LoPro) treated with the novel antifungal olorofim. 30<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases, Paris, France, 18-21 April 2020 (abstract 2585).
- 129. Maertens M, Rijnders B, Thompson G, Fitton L, Rex J, Chen S. An open-label study of the novel antifungal olorofim for the treatment of invasive mould disease in patients with limited treatment options: an overview of the study design,

patient demographics, and range of pathogens identified. 30<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases, Paris, France, 18-21 April 2020 (abstract).

- 130. Tio, SY, Thursky K, Ng G, Rex JH, Carney D, Slavin M. Olorofim for a case of severe disseminated *Lomentospora prolificans* infection. 30th European Congress of Clinical Microbiology and Infectious Diseases, Paris, France, 18-21 April 2020 (abstract 118).
- 131. Thompson GR, Fitton L, Harvey E, Rex J. Disseminated coccidioidomycosis treated with olorofim. 30th European Congress of Clinical Microbiology and Infectious Diseases, Paris, France, 18-21 April 2020 (abstract 3203).
- 132. Cornelissen K, Rex JH, Allen G, Steiner J, Kennedy T. An Open-Label Study in Healthy Volunteers to Evaluate the Effect of Fluconazole upon the Pharmacokinetics of Olorofim. 31st European Congress of Clinical Microbiology and Infectious Diseases (online) 9-12 Jul 2021 (abstract 01080).
- 133. Cornelissen K, Law D, Kennedy T, Rex J H, Townley S, Johnson S, Ayrton J. Tissue distribution of (<sup>14</sup>C)-olorofim following intravenous dosing in the rat. 31<sup>st</sup> European Congress of Clinical Microbiology and Infectious Diseases (online) 9-12 Jul 2021 (abstract 01077).
- 134. Walsh T, Witting B, Robb K, Finkelsztein E, Spagnoletti J, Rex J, Small C. Treatment of *Scedosporium* Mycetoma Refractory to Voriconazole with Olorofim. 31<sup>st</sup> European Congress of Clinical Microbiology and Infectious Diseases (online) 9-12 Jul 2021 (abstract).
- 135. Zerbe C, Rex J, Sabo M, Shoham S. Improvement of Aspergillus udagawae Infection with Olorofim Therapy in the setting of Chronic Granulomatous Disease. 31<sup>st</sup> European Congress of Clinical Microbiology and Infectious Diseases (online) 9-12 Jul 2021 (abstract).
- 136. Morrissey O, Garlick J, Gaffney N Harvey E, Rex J. Long-term Use of Olorofim in the Treatment of Scedosporium apiospermum Chest Wall Infection. 31st European Congress of Clinical Microbiology and Infectious Diseases (online) 9-12 Jul 2021 (abstract).
- 137. Thompson GR, Colamartino J, Trigg K, Harvey E, Rex J: Treatment of Disseminated Coccidioidomycosis with Olorofim. Mycoses Study Group – Education & Research Consortium (MSGERC) 2022, 7-9 Sep 2022, Albuquerque, NM. Abstract.
- 138.Cornelissen K, Wright J, Cristinacce A, Galbraith H, Bruggeman R, Maertens J, Thompson GR, Chen SC-A, Rex, J. Olorofim (OLO) for treatment of invasive mould infections in patients with limited or no treatment options: PK data from a Phase 2b open-label study (NCT03583164, Study 32). IDWeek 2022, 18-22 Oct 2022, Abstract #595.
- 139.Cornelissen K, Newell P, Rex JH, Galbraith H, Isreal S, Bush J. An Open-Label Study in Healthy Volunteers to Determine the Absolute Bioavailability of, the Effect of Food and Dosing by Nasogastric Tube upon the Pharmacokinetics of a Single Oral Dose of Olorofim (OLO). IDWeek 2022, 18-22 Oct 2022, Abstract #594.
- 140.Maertens J, Thompson GR, Spec A, Hammond S, Rijnders B, White PL, Cornely O, Fitton L, Dane A, Rex J, Chen S. Olorofim for treatment of invasive fungal infections (IFI) due to moulds in patients with limited or no treatment options: Interim results from a Phase 2b open-label study (NCT03583164, Study 32). IDWeek 2022, 18-22 Oct 2022, Abstract #754.
- 141.Maertens J, Verweij P, Lanuza E, Harvey E, Dane A, Zinzi D, Rex J, Chen SC. Olorofim for the treatment of invasive mould infections (IMI) in patients with limited or no treatment options: Comparison of interim results from a Phase 2b open-label study with outcomes in historical control populations (NCT03583164, Study 32). IDWeek 2022, 18-22 Oct 2022, Abstract #870.
- 142. Monica Slavin, Johan Maertens, Sharon Chen, Christopher Heath, Martin Hoenigl, Orla Morrissey, Hong Nguyen, David Paterson, George Thompson, Stephen Walsh, Daniela Zinzi, Lesley Fitton, Harvey Emma, and John Rex. Outcomes of invasive fungal infections (IFI) due to Lomentospora prolificans infections treated with olorofim. 33rd European Congress of Clinical Microbiology and Infectious Diseases (Copenhagen) 14-18 April 2021 (abstract O1135).
- 143.Sarah Hammond, Chris Heath, Martin Hoenigl, Andrej Spec, Daniela Zinzi, Emma Harvey, and John Rex. Outcomes in a clinical trial cohort of patients with invasive Scopulariopsis infections treated with olorofim.. 33rd European Congress of Clinical Microbiology and Infectious Diseases (Copenhagen) 14-18 April 2021 (abstract O1141).
- 144.Methee Chayakulkeeree, Anupop Jitmuang, Emma Harvey, Daniela Zinzi, John H. Rex. Successful Treatment of Refractory Invasive Aspergillosis with a Novel Antifungal Agent Olorofim in a Leukemia Patient: A Case Report. 11th Trends in Medical Mycology (TIMM-11), 20-23 October 2023, Athens, Greece (abstract P389).

- 145.Daniela Zinzi, Mike Birch, Emma Harvey, John Rex, Johan Maertens, Jason Oliver, Sharon Chen. Outcomes of invasive fungal disease in a subgroup of patients receiving olorofim/azole combination in an open label salvage study. 11th Trends in Medical Mycology (TIMM-11), 20-23 October 2023, Athens, Greece (abstract P412).
- 146.Karen Cornelissen, Daniela Zinzi, John H Rex, Hal Galbraith, Joel Neutel, Thomas Marbury. A Phase I, Single-dose, Parallel Group Study to Assess the Pharmacokinetics of Olorofim in Subjects with Hepatic Impairment. 11th Trends in Medical Mycology (TIMM-11), 20-23 October 2023, Athens, Greece (abstract P437).
- 147.Karen Cornelissen, Daniela Zinzi, John H Rex, Hal Galbraith, Kwabena Ayesu. A Phase I, Single-dose, Parallel Group Study to Assess the Pharmacokinetics of Olorofim in Subjects with Renal Impairment. 11th Trends in Medical Mycology (TIMM-11), 20-23 October 2023, Athens, Greece (abstract P439).
- 148.Andrej Spec, Mike Birch, Corinne Pinder, Emma Harvey, Daniela Zinzi, John Rex. Clinical outcome in a US patient with A.ustus complex pulmonary invasive aspergillosis treated with olorofim in a Phase2b study (NCT03583164). 11th Trends in Medical Mycology (TIMM-11), 20-23 October 2023, Athens, Greece (abstract P471).
- 149.Cornelissen K, Rex JH, Zinzi D, Galbraith H, Burt HJ. Assessment of body weight upon PK of olorofim in patients with invasive mould infections. IDWeek 2024 (Los Angeles), 16-19 Oct 2024, Abstract P-1238.
- 150.Cornelissen K, Rex JH, Zinzi D Bruggemann R, Wright J. Systemic exposure of olorofim in children with invasive fungal infections. IDWeek 2024 (Los Angeles), 16-19 Oct 2024, Abstract P-1239.
- 151.Fariba M. Donovan, George R Thompson, Royce H. Johnson, Rasha A. Kuran, Thomas F Patterson, Martin Hoenigl, Joanna M. Schaenman, Shmuel Shoham, Steven M Holland, Monica K Sikka, Andrej Spec, Mark Bresnik, John N Galgiani, John H Rex. Novel Antifungal Olorofim Use in Intractable CNS and Non-CNS Disseminated Coccidioidomycosis. IDWeek 2024 (Los Angeles), 16-19 Oct 2024, Presentation 95.

### **G. Major Presentations at National and International Meetings**

- 1. XII Congress of the International Society for Human and Animal Mycology, March 1994, Adelaide, Australia. Speaker in symposium "Update on the management of fungal infections," with lecture entitled "Fluconazole vs. amphotericin B as therapy of candidemia in non-neutropenic patients."
- 2. 31st Annual William J. Holloway Infectious Disease Symposium of the Medical Society of Delaware, May, 1994, Wilmington, DE. Lecture entitled "Recent advances in the management of systemic *Candida* infections."
- 94th General Meeting of the American Society for Microbiology, May 1994, Las Vegas, NV. Speaker in symposium entitled "Research developments in the clinical mycology laboratory," with lecture entitled "Antifungal susceptibility testing."
- 4. 24th Annual Meeting of the Society for Critical Care Medicine, February 1995, San Francisco, CA. Speaker in symposium entitled "Diagnosis and treatment of fungal infectious in critically-ill patients," with lecture entitled "Treatment of *Candida* bloodstream infections."
- 5. Focus on Fungus V (sponsored by the University of Texas Health Science Centers of San Antonio and Houston), March 1995, San Francisco, CA. Lecture entitled "Recent advances in the management of *Candida* bloodstream infections."
- 6. FDA Antiviral and Antifungal Drug Division Advisory Board, April, 1995, Bethesda, MD. Lecture entitled "Design issues in therapy trials for invasive candidiasis."
- 7. International Advisory Board for the Management of Invasive Candidiasis (sponsored by Harbor-UCLA Medical School), April, 1995, Torrance, CA.
- 8. 95th General Meeting of the American Society for Microbiology, May 1995, Washington, DC. Speaker in symposium entitled "Contemporary issues in antifungal susceptibility testing: Beyond the NCCLS reference method," with lecture entitled "Pitfalls in establishing clinical relevance for antifungal susceptibility testing."
- 9. Trends in Fungal Infections III (sponsored by the European Organization for Research on Treatment of Cancer), September 7-9, 1995, Brussels, Belgium. Lecture entitled "Treatment of serious *Candida* infections."
- 10. 25th Annual Meeting of the Society for Critical Care Medicine, February 1996, New Orleans, LA. Speaker in symposium entitled "Management of infections in the critically-ill patient: Focus on *Candida* and *Enterococci*," with lecture entitled "Epidemiology, risk factors, and treatment strategies for invasive candidiasis in the critically-ill patient."
- 11. ASM Conference on *Candida* and Candidiasis: Biology, Pathogenesis, and Management, March 24-27, 1996, San Diego, CA. Speaker in symposium entitled "Candidiasis: Epidemiology and treatment," with lecture entitled "Disseminated *Candida* syndromes in non-neutropenic patients: current status and future directions."

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- 12. 36th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 1996, New Orleans, LA. Convenor of symposium entitled "Antifungal drug resistance: Problems & perspectives," with lecture entitled "Current therapeutic approaches to antifungal drug resistance."
- 13. 34th Annual Meeting of the Infectious Diseases Society of America and the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 1996, New Orleans, LA. Speaker in symposium entitled "Frontiers of antimicrobial susceptibility testing: When procedures meet reality," with lecture entitled "Antifungal susceptibility testing: The clinical relevance of resistance *in vitro*."
- 14. 34th Annual Meeting of the Infectious Diseases Society of America, September 1996, New Orleans, LA. Co-convenor of a *Meet the Professor* session entitled "Management of fungal infections."
- Focus on Fungus VII (sponsored by the University of Texas Health Science Center—San Antonio), March 1997, San Antonio, TX. Lecture entitled "Point-counterpoint: Management of vascular catheters in candidemia."
- 16. 97th General Meeting of the American Society for Microbiology, May 1997, Miami Beach, FL. Co-convenor of symposium entitled "Epidemiology and control of medically important fungi," with lecture entitled "Antifungal resistance."
- 8<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases, May 1997, Lausanne, Switzerland. Coconvenor of symposium entitled "Susceptibility testing of yeasts," with lecture entitled "Antifungal susceptibility testing: New NCCLS interpretive guidelines."
- 18. 13<sup>th</sup> Congress of the International Society for Human and Animal Mycology, June 1997, Parma, Italy. Organizer and co-convenor of a workshop entitled "Alternative Endpoints and Trial Designs for Clinical Trials of Antifungal Agents: Current Status, Future Directions."
- 19. 13<sup>th</sup> Congress of the International Society for Human and Animal Mycology, June 1997, Parma, Italy. Co-convenor of symposium entitled "The role of immunoreconstitution in the management of refractory opportunistic fungal infections," with lecture entitled "Immunity to fungal infections."
- 20. 13<sup>th</sup> Congress of the International Society for Human and Animal Mycology, June 1997, Parma, Italy. Speaker in symposium entitled "Antifungal drug resistance in pathogenic fungi," with lecture entitled "Beyond *Candida* and azoles: Antifungal resistance in other settings."
- 21. 13<sup>th</sup> Congress of the International Society for Human and Animal Mycology, June 1997, Parma, Italy. Speaker in symposium entitled "The growing importance of non-*albicans Candida* species as opportunistic pathogens," with lecture entitled "Treatment of non-*albicans Candida* infections."
- 22. 21<sup>st</sup> International Congress of Chemotherapy, Sydney, Australia, July 1997. Speaker in a symposium entitled "Laboratory Support for Diagnosis and Management of Fungal Infections," with lecture entitled "Clinical Relevance of Antifungal Susceptibility Testing and Emerging Azole Resistance."
- 23. 35<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, September 1997, San Francisco. Co-convenor of a symposium entitled "Molecular Strategies for Antifungal Therapy: New Approaches to Resistant Infections."
- 24. 37th Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada, September 1997. Speaker in a symposium entitled "Clinical Evaluation of Antifungals," with lecture entitled "Problems and Solutions to Clinical Trial Design."
- 25. 5<sup>th</sup> Deep Mycoses Forum, February, 1998, Tokyo, Japan. Lecture entitled "Treatment of invasive fungal infections: Lessons from susceptibility testing."
- 26. Focus on Fungus VIII (sponsored by the University of Texas Health Science Center—San Antonio), March 1998, Orlando. FL. Lecture entitled "Point-counterpoint: Use of lipid-associated amphotericin B preparations."
- 27. Transplant Infectious Disease World Congress (sponsored jointly by the American Society for Transplant Physicians, the Centers for Disease Control and Prevention, the International Immunocompromised Host Society, and the Transplantation Society, April, 1998, Orlando, FL. Lecture entitled "Itraconazole and fluconazole in the treatment of fungal infection in transplant patients."
- 8<sup>th</sup> International Congress on Infectious Diseases (sponsored by the International Society for Infectious Diseases), May, 1998, Boston, MA. Lecture entitled "Treatment of *Candida* infections: Lessons from susceptibility testing."
- 29. 6<sup>th</sup> International Mycology Congress, August, 1998, Jerusalem, Israel. Lecture entitled "Antifungal resistance: The clinical relevance of resistance in vitro."
- 30. 38th Interscience Conference on Antimicrobial Agents and Chemotherapy, San Diego, CA, September 1998. Coconvenor of a *Meet the Expert* session entitled "Management of fungal infections."

- 31. 28th Annual Meeting of the Society for Critical Care Medicine, January 1999, San Francisco, CA. Speaker in symposium entitled "Update in Infectious Diseases," with lecture entitled "Antifungal agents in immunosuppressed patients: What is the role of lipid formulations of amphotericin B?"
- 32. ASM Conference on *Candida* and Candidiasis: Biology, Pathogenesis, and Management, March 1-4, 1999, San Diego, CA. Speaker in symposium entitled "Antifungal Resistance," with lecture entitled "Antifungal susceptibility testing: What we do and do not know."
- 33. 4<sup>th</sup> International Antifungal Drug Discovery and Development Summit, March 10-11, 1999, Princeton, NJ. Keynote address: "New antifungal agents: Current needs and barriers to development."
- 34. 9th Annual Scientific Meeting of the Society for Healthcare Epidemiology of America, April 18-20, 1999, San Francisco, CA. Organizer and chairman of workshop entitled "Emerging nosocomial fungi," with lecture entitled "Antifungal resistance."
- 35. 1999 Harold C. Neu Infectious Diseases Conference, May 20-23, 1999, Philadelphia, PA. Organizer and chairman of session entitled "Fungal infections," with lecture entitled "Pharmacodynamics of antifungal agents: Implications for interpretation of susceptibility testing and drug dosing."
- 36. IX<sup>th</sup> International Congress of Bacteriology and Applied Microbiology and IX<sup>th</sup> International Congress of Mycology, August 16-20, 1999, Sydney, Australia. Speaker in plenary session entitled "Fungal resistance in medicine, food, and biodeterioration," with lecture entitled "Relevance of fungal resistance in medicine."
- 37. IX<sup>th</sup> International Congress of Bacteriology and Applied Microbiology and IX<sup>th</sup> International Congress of Mycology, August 16-20, 1999, Sydney, Australia. Speaker in symposium entitled "Serious fungal infections: Present and future treatment strategies," with lecture entitled "Pushing the envelope: Pharmacodynamic insights and the potential utility of combination therapy."
- 38. 39th Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, CA, September 1999. Coconvenor of a symposium entitled "New Frontiers in Antifungal Resistance."
- 39. 29th Annual Meeting of the Society for Critical Care Medicine, February 2000, Orlando, FL. Speaker in symposium entitled "Issues in Infectious Diseases," with lecture entitled "Anti-fungal Resistance: Is it a problem in the ICU?"
- 40. Focus on Fungus X (sponsored by the University of Texas Health Science Center—San Antonio), March 2000, Atlanta. FL. Lecture entitled "Invasive candidiasis: Species Old & New, Therapies Tried & True."
- 41. 14<sup>th</sup> Congress of the International Society for Human and Animal Mycology, May 2000, Buenos Aires, Argentina. Speaker in symposium entitled "Superficial and invasive infections caused by *Candida* and other emerging yeasts," with lecture entitled "Treatment of candidemia in the non-neutropenic host."
- 42. 14<sup>th</sup> Congress of the International Society for Human and Animal Mycology, May 2000, Buenos Aires, Argentina. Lecture entitled "Correlation between in vitro susceptibility test results and clinical response."
- 43. 38<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, September 2000, New Orleans, LA. Speaker in a symposium entitled "Formulary 2000," with a lecture entitled "Current and future antifungal agents."
- 44. 40th Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada, September 2000. Speaker in a symposium entitled "New antimicrobials," with a lecture entitled "Echinocandin antifungal agents."
- 45. Focus on Fungus XI, March 2001, Washington, DC. Lecture entitled "Alternative Trial Designs and Evaluation Strategies for Studies of New Antifungal Agents."
- 46. 11<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Istanbul, Turkey, April 2001. Speaker and convenor of a symposium entitled "Transatlantic Controversies in the Management of Serious Fungal Infections," with a lecture entitled "Are we ready for prophylaxis in the ICU?"
- 47. 49th Annual Meeting of the Japanese Society of Chemotherapy, Yokohama, Japan, May 2001. Speaker in a symposium entitled "A new class of anti-fungal agent: Candins," with a lecture entitled "Current understanding and future expectations of Candins in antifungal therapy"
- 48. Trends in Invasive Fungal Infections 6, Prague, Czech Republic, October 2001. Speaker in a symposium entitled "Opening Plenary Session," with a lecture entitled "Animal Models—Are they of Clinical Relevance?"
- 49. 39<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, October 2001, San Francisco, CA. Speaker in a symposium entitled "New Antifungals: From Bench to Bedside," with a lecture entitled "Impact of Echinocandins."

- 50. 41<sup>st</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, December 2001. Speaker in a symposium entitled "Conundrums in Medical Mycology," with a lecture entitled "Alternative Trial Designs for Testing Antifungal Agents."
- 51. 1<sup>st</sup> Annual John E. Bennett Forum on Clinical Trial Design, New York City, January 2002. Lecture entitled "Licensure of agents for therapy of aspergillosis."
- 52. Focus on Fungus XII, March 2002, Phoenix, AZ. Moderator of session entitled "Interesting Case Reports An Interactive Session."
- 53. 9<sup>th</sup> Annual Meeting of the Korean Society for Medical Mycology, July 2002, Seoul, Korea. Plenary lecture entitled "Antifungal Agents: Old Questions, New Tools, and New Questions."
- 54. 42<sup>nd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, San Diego, September 2002. Speaker in a symposium entitled "New Antifungal Drugs, New Choices," with a lecture entitled "What is the role of combination antifungals?"
- 55. 40<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, October 2002, Chicago, IL. Moderator of and speaker in a symposium entitled "Formulary 2002," with a lecture entitled "Voriconazole and other new azoles."
- 56. 2<sup>nd</sup> Annual John E. Bennett Forum on Clinical Trial Design, New York City, January 2003. Lecture entitled "Design of the caspofungin v. placebo trial in (S)ICU patients and use of risk factors in trial design."
- 57. 13th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Glasgow, United Kingdom, May 2003. Keynote lecture entitled "New opportunities in the therapy of fungal diseases."
- 58. 15<sup>th</sup> Congress of the International Society for Human and Animal Mycology, May 2003, San Antonio, Texas. Keynote lecture entitled "Future of Medical Mycology: A Clinical View."
- 59. 43<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, September 2003. Convenor of a symposium entitled "Pharmacodynamics of Antifungals"
- 60. 9<sup>th</sup> Congress of the European Confederation of Medical Mycology and the 7<sup>th</sup> Trends in Invasive Fungal Infections, Amsterdam, The Netherlands, September 2003. Plenary lecture entitled "New Drug Discoveries."
- 61. 41<sup>st</sup> Annual Meeting of the Infectious Diseases Society of America, October 2003, San Diego, CA. Poster review faculty.
- 62. ASM Conference on *Candida* and Candidiasis: Biology, Pathogenesis, and Management, March 18-21, 2004, Austin, TX. Keynote speaker with lecture entitled "Future Directions in Antifungal Discovery."
- Infectious Diseases Society of America International Society of Anti-Infective Pharmacology Food and Drug Administration co-sponsored Antimicrobial Drug Development Workshop, April 15-16, 2004, Washington, DC. Invited panelist.
- 64. 2004 Meeting of the British Society for Medical Mycology, 19-20 April 2004, Bradford, UK. Plenary lecture entitled "The future of medical mycology: An industry perspective."
- 65. 3rd Annual Conference on Antimicrobial Resistance, June 2004, Washington, DC. Chair keynote symposium entitled "Developing treatments for infections with no market pull: The example of the medicines for malaria venture."
- National Institute of Allergy and Infectious Disease (NIAID)-sponsored summit on Antimicrobial Availability, August 19-20, 2004, Washington, DC. Invited speaker & panelist.
- 67. 42<sup>nd</sup> Annual Meeting of the Infectious Diseases Society of America, October 2004, Boston, MA. Poster review faculty.
- 68. 44<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington, DC, November 2004. Presentation entitled "Current therapy of candidal infections."
- 69. Focus on Fungal Infections 15, March 2005, Miami, FL. Keynote lecture entitled "Discovery and development of antimicrobial agents: Meeting the challenges of generic agents, regulatory guidelines, efflux pumps, and points between."
- 70. Annual meeting of Danish Infectious Diseases Society, May 2005, Middelfart, Denmark. Keynote lecture entitled "Therapy for candidemia."
- 71. 4th Annual Conference on Antimicrobial Resistance, June 2005, Washington, DC. Chair symposium entitled "Economics of Antimicrobial Resistance."
- 72. 45<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, LA, September 2005. Chair a symposium entitled "Antifungal Susceptibility Testing" and give a presentation entitled "Susceptibility -- the CLSI approach."

- 73. 45<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, LA, September 2005. Chair a symposium entitled "The 'critical path' to antimicrobial drug development" and give a presentation entitled "Drug development from the pharmaceutical side."
- 74. Gordon Research Conference entitled "New Antibacterial Discovery & Development", March 5-10, 2008, Ventura, CA. Invited speaker with a talk entitled "The Fourth Horseman, Pestilence."
- 75. AbstrNijmegen European Mycology Therapy Consensus Panel, May 2006, Nijmegen. Participant, with talk entitled "Antifungal therapy in the ICU."
- 76. 5th Annual Conference on Antimicrobial Resistance, June 2006, Washington, DC. Chair symposium entitled "Pharmacological predictors of outcome: Can they be used to treat or prevent resistance? What is their role in drug development?"
- 77. 44<sup>nd</sup> Annual Meeting of the Infectious Diseases Society of America, October 2006, Toronto, Canada. Chair a symposium entitled "Antifungal Formulary 2006."
- 78. 40<sup>th</sup> Anniversary Symposium of Paul-Ehrlich-Society for Chemotherapy, April 30-May 2007, Königswinter, Germany. Participant, with talk entitled "Industry perspective on development of new antimicrobial agents."
- 79. 6th Annual Conference on Antimicrobial Resistance, June 2007, Washington, DC. Participant, with talk entitled "Drug resistance in fungal infections."
- 6th Annual Conference on Antimicrobial Resistance, June 2007, Washington, DC. Chair symposium entitled "Drugresistant Mycobacterium tuberculosis: Looking Back, Looking Forward."
- 81. 45<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, October 2007, San Diego, CA. Chair a symposium entitled "Update on Fungal Treatment Guidelines."
- 82. Gordon Research Conference entitled "New Antibacterial Discovery & Development", March 9-14, 2008, Lucca, Italy. Invited speaker with a talk entitled "Clinical considerations for a new antibiotic."
- 83. Joint 48<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy / 46th Annual Meeting of the Infectious Diseases Society of America, October 2008, Washington, DC. Chair a symposium entitled "Update on the Antifungal Formulary." Invited speaker with a talk entitled "Perspectives of the Pharmaceutical Industry."
- 84. Innovative Incentives for Effective Antibacterials, September 17, 2009, sponsored by the Swedish EU Presidency, Stockholm, Sweden. Invited speaker with a talk entitled "Perspectives of the Pharmaceutical Industry."
- 85. Public Health Emergency Medical Countermeasures Enterprise, February 22-24, 2010, An Institute of Medicine Workshop sponsored by the Institute of Medicine, Washington, DC. Invited speaker for plenary session with a talk entitled "Commercial Challenges: Perspectives from big pharma."
- 86. Public Health Emergency Medical Countermeasures Enterprise, February 22-24, 2010, An Institute of Medicine Workshop sponsored by the Institute of Medicine, Washington, DC. Panelist for a panel discussion entitled "Strategies to Improve Portfolio Management: Translating Basic Science."
- EFPIA (European Federation of Pharmaceutical Industries and Associations), 2010 Annual Meeting (21 June 2010), Chair a symposium entitled "Antibiotics - Re-energising R&D to meet society's needs."
- 88. Antibacterial Resistance and Diagnostic Device and Drug Development Research for Bacterial Diseases; A Public Workshop Co-Sponsored by the Food and Drug Administration, the National Institute of Allergy and Infectious Diseases, and the Infectious Diseases Society of America. July 26-27, 2010, Silver Spring, MD. Member of the program planning committee and an invited speaker with a talk entitled "Drug discovery: Industry perspective."
- 89. 20<sup>th</sup> Annual Meeting of the Society of Infectious Diseases Pharmacists, 11 Sep 2010, Boston, MA. Invited speaker (Meet-the-Expert Session) with a talk entitled "Industry Perspective on the Antimicrobial Pipeline"
- 90. 50<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, 12-15 Sep 2010, Boston, MA. Invited symposium speaker with a talk entitled "Does the Anti-infective Pharmaceutical Industry need a stimulus package?"
- 91. Workshop on Antibacterials, 7-8 Feb 2011, European Medicines Agency, London, UK. Team leader for EFPIA Antimicrobial Working Group Presentation team, presenter for discussion materials on "Development of Drugs for Skin Infections" and "Development of Drugs for Bacteremia."
- 92. Advancing Regulatory Science for Medical Countermeasure Development: An Institute of Medicine Workshop sponsored by the Institute of Medicine, Washington, DC. Workshop Co-Chair.

- 93. 21<sup>st</sup> Annual European Conference on Clinical Microbiology and Infectious Diseases and the 27<sup>th</sup> International Conference on Chemotherapy 7-10 May 2011, Milan, Italy. Speaker in a symposium entitled "Antifungal drugs make me mad: Azoles vs. Candins" with a lecture entitled "Azoles."
- 94. 21<sup>st</sup> Annual European Conference on Clinical Microbiology and Infectious Diseases and the 27<sup>th</sup> International Conference on Chemotherapy 7-10 May 2011, Milan, Italy. Convenor for a symposium entitled "Antifungal Management Strategies."
- 95. 21<sup>st</sup> Annual European Conference on Clinical Microbiology and Infectious Diseases and the 27<sup>th</sup> International Conference on Chemotherapy 7-10 May 2011, Milan, Italy. Speaker in a symposium entitled 'Bad Bugs Need Better Drugs' with a lecture entitled "The Search for New Tools: The R&D Challenge."
- 96. Pew Trust-IDSA-PhRMA workshop, "Reviving the Pipeline of Life-Saving Antibiotics: Exploring Solutions to Spur Innovation", 22 Sep 2011, Washington, DC. Speaker in a session entitled "Overcoming Antibiotics' Unique Scientific and Regulatory Challenges" with a lecture entitled "Overcoming the unique scientific and regulatory challenges of antibiotics (Industry Perspective)."
- 97. EU-US (European Commission, NIAID) workshop, "Challenges And Solutions In The Development Of New Diagnostic Tests To Combat Antimicrobial Resistance", 28-29 Sep 2011, Brussels, Belgium. Keynote speaker with a lecture entitled "The importance of rapid diagnostics for advancing antibacterial development."
- 98. Gordon Research Conference entitled "New Antibacterial Discovery & Development", April 15-20, 2012, Lucca, Italy. Invited speaker with a talk entitled "Trial feasibility and relevance of endpoints - the industry view."
- 99. Engelberg Center for Health Care Reform at the Brookings Institution workshop entitled "Facilitating Antibacterial Development", May 9, 2012, Washington, DC. Invited speaker with a talk entitled "Novel Approaches to Further Antibacterial Drug Development: New Approaches to the Clinical Development Program — the Industry View."
- 100. Clinical Trials Transformation Initiative-US FDA workshop entitled "Anti-Bacterial Drug Development: Issues in the Design of Trials in Patients with Unmet Need and in Patients with Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia", October 10-11, 2012, Arlington, VA. Invited speaker with a talk entitled "Novel Approaches to Further Antibacterial Drug Development: New Approaches to the Clinical Development Program" and panelist in a session entitled "Identifying potential solutions to development of drugs for unmet need."
- 101. Workshop on Antibacterials, 25-26 October 2012, European Medicines Agency, London, UK. Team leader for EFPIA Antimicrobial Working Group Presentation team, presenter for discussion materials on "Diagnostics."
- 102. Pew Trust workshop, "A New Pathway for Antibiotic Innovation: Exploring Drug Development for Limited Populations," 1 Jan 2013, Washington, DC. Speaker in a session entitled "Defining the Limited Population Regulatory Pathway: What It Is, What It Does, and Why It Is Needed."
- 103. Engelberg Center for Health Care Reform at the Brookings Institution workshop entitled "Incentives for Change: Addressing the Challenges in Antibacterial Drug Development," 27 Feb 2013, Washington, DC. Discussant.
- 104. 53<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, 10–13 September 2013, Denver, Colorado. Invited speaker in a symposium entitled "Using Pharmacokinetics-Pharmacodynamics to Set In Vitro Susceptibility Breakpoints" with a talk entitled "New pathways for antibiotics for highly resistant pathogens: The fundamental role of PK-PD in Tier B and Tier C development programs"
- 105. Aligning Incentives for Antibiotic Development and Use With Public Health Needs. Chatham House Centre on Global Health Security Roundtable, 2 Oct 2013. Panelist in session entitled "Integrating Incentives for Development with Incentives for Conservation."
- 106. Antimicrobial Resistance: Incentivizing Change towards a Global Solution, Chatham House Centre on Global Health Security Workshop, 3-4 Oct 2013, London, UK. Invited speaker in a session entitled "New approaches to diagnosis and discovery" with a talk entitled "How can new diagnostics aid clinical trials?"
- 107. 6th Trends in Medical Mycology (TIMM-6), 11-14 October 2013, Copenhagen, Denmark. Plenary speaker with a talk entitled "The landscape of antifungal development, present and future."
- 108. FDA Anti-infective Drugs Advisory Committee (AIDAC), 17 Oct 2013, Silver Spring, MD. Invited speaker with a presentation entitled "The integral role of PK-PD in the development and maintenance of interpretive criteria."
- 109. Engelberg Center for Health Care Reform at the Brookings Institution workshop entitled "Modernizing antibacterial drug development and promoting stewardship", Feb 7, 2014, Washington, DC. Invited panelist in a session entitled "Targeting drug development for patients with serious bacterial diseases and unmet medical needs."

- 110. 6<sup>th</sup> Advances Against Aspergillosis, 27 Feb to 1 Mar 2014, Madrid, Spain. Invited speaker with a presentation entitled "New agents for aspergillosis: Development pathways and economic pull."
- 111. 6th Advances Against Aspergillosis, 27 Feb to 1 Mar 2014, Madrid, Spain. Co-chair of a symposium entitled "Clinical and scientific future of early anti-Aseprgillus agents."
- 112. Development of New Antibacterial Products: Charting a Course for the Future, NIH-FDA-Sponsored Workshop, 30-31 July 2014, Bethesda, MD. Invited speaker in a session entitled "Streamlined Antibacterial Drug Development Pathways Targeting Unmet Need" with a talk entitled "A Comprehensive Framework to Address the Unmet Need for New Antibacterial Treatments."
- 113. Development of New Antibacterial Products: Charting a Course for the Future, NIH-FDA-Sponsored Workshop, 30-31 July 2014, Bethesda, MD. Invited speaker in a session entitled "The Role of Diagnostic Tests—Current State and Utility in Antibacterial Drug Development" with a talk entitled "Industry Perspective."
- 114. 54<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, 5-9 September 2014, Washington, DC. Keynote speaker with a lecture entitled "Enabling drug discovery & development to address the crisis of antimicrobial resistance: New tools, new pathways, & remaining challenges."
- 115. Coordinated Development of Diagnostics & Therapeutics, NIH-FDA-Sponsored Workshop, 24-25 September 2014, Bethesda, MD. Invited speaker with a talk entitled "Coordinated Diagnostics & Therapeutics: A Clinician Developer's Overview."
- 116. Engelberg Center for Health Care Reform at the Brookings Institution workshop entitled "Reinvigorating the oral antibacterial development pipeline," November 20, 2014, Washington, DC. Invited speaker with a talk entitled "Challenges with oral antibacterials."
- 117. FDA Anti-infective Drugs Advisory Committee (AIDAC), 4 Dec 2014, Hyattsville, MD. Invited speaker representing BIO (Biotechnology Industry Organization), with a presentation entitled "Balancing Expectations: Dataset Size vs. Feasibility: Implications for labeling."
- Bioinfect Conference 2014, 4 Dec 2014, Alderley Park, UK. Invited speaker with a presentation entitled "Commercial Models."
- 119. Enabling Rapid Response with Medical Countermeasures to Mitigate Risk of Emerging Infectious Diseases, March 26-27, 2015, An Institute of Medicine Workshop sponsored by the Institute of Medicine, Washington, DC. Member of program committee, session chair, and speaker in a session entitled "Sustainability and Maintenance of Business Models to Ensure Rapid and Nimble Response to Emerging Threats."
- 120. BIO BiotechnologyIndustry Organization Annual Convention, 15-18 June 2015, Philadelphia, PA. Panelist in an interactive symposium entitled "Redefining Infectious Disease:Bacteria in Health and Sickness."
- 121. Mapping the treatment journey to inform the patient-centred development of antibiotics and diagnostics, a workshop sponsored by the Wellcome Trust, 16-17 July 2015, London, UK. Panelist in a session entitled "A physician's treatment reality: examples sepsis and otitis media."
- 122. 55<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, 17-21 September 2015, San Diego, CA. Panelist in an interactive session entitled "I have a White Powder and Want a Drug: Shepherding New Compounds Across the Valley of Death."
- 123. 36<sup>th</sup> American College of Toxicology Annual Meeting, 8-11 Nov 2015, Summerlin, NV. Keynote speaker with a lecture entitled "Enabling drug discovery & development to address the crisis of antimicrobial resistance: New tools, new pathways, & remaining challenges."
- 124. Workshop on PK-PD for Antibacterial PK-PD, 12-13 Nov 2015, European Medicines Agency, London, UK. Team leader for EFPIA Antimicrobial Working Group Presentation team and presenter for discussion materials on "Replacing and Interpreting Clinical Data."
- 125. 12<sup>th</sup> Annual DIA (Develop Innovate Advance) Japan, 15-17 Nov 2015, Tokyo Big Sight Ariake. Speaker with a lecture entitled "Evolution of the regulatory framework in the US and EU to support streamlined development of new antibiotics" in a session entitled "To Fight Against Superbugs Future Development of Antibacterial Drugs Surrounding Drug-Resistant Pathogens."
- 126. New Frontiers in Antibacterial Resistance Research, 20-21 Jan 2016, Stockholm. Speaker with lecture entitled "Overview of Challenges in the Conduct of Interventional Trials to Address Antibacterial Resistance."

- 127. EU-US Collaboration on clinical trials related to antimicrobial resistance, 21-22 Jan 2016, Stockholm, Sweden. Keynote speaker with lecture entitled "Clinical research on AMR: Current pipeline, development issues, and ideas for ways forward"
- 128.53rd Annual William J. Holloway Infectious Disease Symposium of the Medical Society of Delaware, May, 2016, Wilmington, DE. Lecture entitled "Enabling drug discovery & development to address the crisis of antimicrobial resistance: New tools, new pathways, & remaining challenges."
- 129.DRIVE-AB mid-term congress on stimulating innovation, sustainable use, and global access to antibiotics, 2 June 2016, Amsterdam, The Netherlands. Panelist in a session entitled "New Economic models for antibiotic innovation"
- 130.FDA Public Workshop on Facilitating Antibacterial Drug Development for Patients With Unmet Need and Developing Antibacterial Drugs That Target a Single Species. July 18–18, 2016, Washington, DC. Speaker in session entitled "Challenges with Clinical Trial Design for a Drug Targeting a Single Species of Bacteria" with speaker and convenor for a session entitled "Developing narrow-spectru agents: The example of Drug X-1."
- 131.ESCMID-ASM Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance, 21–23 September 2016, Vienna, Austria. Plenary speaker with a talk entitled "Drug development within the context of AMR: giving new molecules the best chance"
- 132.ASM Conference on Antibacterial Development, December 11–14, 2016, Washington, DC. Speaker with lecture entitled "CARB-X and support for new tools for management of drug-resistant bacterial infections."
- 133.FDA Public Workshop on Current State and Further Development of Animal Models of Serious Infections Caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa*. March 1, 2017, Washington, DC. Speaker in session entitled "Challenges with Clinical Trial Design for a Drug Targeting a Single Species of Bacteria" with lecture entitled "Trial Design for Narrow-Spectrum Agents: Overview & Drug X-1."
- 134.Solutions for Drug-Resistant Infections, 3-5 April 2017, Brisbane, Australia. Keynote peaker with lecture entitled "Developing new antibacterial products: Perspectives on giving new therapies the best chance."
- 135.NIAID Workshop on PKPD for Development of Therapeutics against Bacterial Pathogens. June 14-15, 2017, Bethesda, MD. Program Committee and Session Co-Moderator for session entitled "Stakeholder feedback and discussion."
- 136.National Academies of Medicine workshop on Combating Antimicrobial Resistance: A One Health Approach to a Global Threat – A Workshop. 20-21 June 2017, Washington, DC. Program Committee and speaker in a session entitled "Strengthening Partnerships and International Cooperation" with a talk entitled "Partnerships to combat AMR."
- 137.ASM-ESCMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance, 6-8 September 2017, Boston, MA. Speaker with a talk entitled "DRIVE-AB – Driving Re-investment in R&D and Responsible Antibiotic Use."
- 138.8th Trends in Medical Mycology (TIMM-8), 6-9 October 2017, Belgrade, Serbia. Speaker with a talk entitled "F901318" in a session entitled "New antifungal drugs in the pipeline."
- 139. Medicines Discovery Catapult Workshop: Next Generation Antibiotics, 16-17 Jan 2018, London, UK. Speaker with a talk entitled "Funding, Filing, & Finance" in a session entitled "Enabling Resources."
- 140.Gordon Research Conference entitled "New Antibacterial Discovery & Development", March 1-5, 2018, Ventura, CA. Invited speaker with a talk entitled "Predictions are difficult, especially when they are about the future: What should you consider as you place your bets for the next 10 years?"
- 141.28<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Madrid, Spain, 21-24 April 2018. Speaker in a symposium entitled "Expediting antibacterial development: core lessons and key tools for a rocky road," with a lecture entitled "Alternatives to (classical) antibiotics: what will it take to convincingly develop a virulence inhibitor or similar indirect agent?" Slides available at http://amr.solutions/blog/eccmid-symposium-expeditingantibacterial-development-core-lessons-and-key-tools-for-a-rocky-road.
- 142.20<sup>th</sup> Congress of the International Society for Human and Animal Mycology, 30 June 4 July 2018, Amsterdam, NL. Keynote lecture entitled "Antifungal drug discovery comes of age."
- 143.20th Congress of the International Society for Human and Animal Mycology, 30 June 4 July 2018, Amsterdam, NL. Talk entitled "Antifungal pipeline session: F901318 - F2G."
- 144.FDA Public Workshop on Development of Non-Traditional Therapies for Bacterial Infections. 21-22 Aug 2018, Washington, DC. Lectures entitled "Overview of non-traditional theraies" and "Case Study Z-3: Reducing risk of infection due to an MBL-producing organism by preventing acquisition of same."

- 145.Gates Grand Challenges, Annual Meeting 15-18 Oct 2018, Berlin, Germany. Chair of a session entitled "Fostering cooperation: Incentivizing AMR R&D."
- 146.Duke University, 2<sup>nd</sup> Annual Drug Discovery Symposium, 9-10 May 2019, Lecture entitled "Antifungal Drug R&D Comes of Age."
- 147.12th Berlin Conference on Life Sciences: Novel Antimicrobials and AMR Diagnostics, 14-15 Mar 2019 (Berlin), Chair of a session entitled "Update and progress report with regard to AMR innovations for human and animal health."
- 148.International Course on Antibiotics and Resistance (ICARe), 19-26 Oct 2019, Annecy, France. Lecture entitled "New pathways to antibiotic registration."
- 149.FDA-IDSA-NIH-Pew Public Workshop, 18-19 Nov 2019, Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development in the United States. Meeting co-organizer with lectures entitled "Antibiotic R&D 3.0: Let's all row the boat together..." and "Meeting Summary"
- 150.Focus on Infection 2020, Royal College of Physicians of Ireland (7 Dec 2020): Lecture entitled "Antibiotics for Unmet Need: The Challenge of New Drugs for Bad Bugs."
- 151.National Academies of Science, Engineering, and Medicine Committee on the Long-Term Medical and Economic Effects of Antimicrobial Resistance: Open Session workshop (5 Jan 2021) entitled The Antimicrobial Product Pipeline and Incentives for Market Viability. Lecture entitled "Pricing of Antibiotics and Proposals to Strengthen the Pipeline."
- 152.Medical Research Council (UK) and The University of Exeter Strategic Workshop (4 May 2021): Drivers of Antifungal Resistance. Lecture entitled "Antifungal Drug R&D Comes of Age"
- 153.Royal Society of Medicine Antimicrobial Innovation Workshop (5 July 2021). Lecture entitled "The future of AMR reimbursement: What types of products will succeed?"
- 154.Best Brains Exchange (Canada): 12-13 Oct 2021 Workshop entitled "Challenges in the Antimicrobial Business Model and Potential Incentives to Increase Access and Promote Innovation" with lecture entitled "Setting the Scene: Challenges in the Antimicrobial Business Model and Potential Incentives to Increase Access and Promote Innovation."
- 155.International Course on Antibiotics and Resistance (ICARe), 16-24 Oct 2021, Annecy, France. Lecture entitled "New pathways to antibiotic registration."
- 156.ASM-ESCMID Joint Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance (7-9 Dec 2021 (virtual). Program Committee and Lecture entitled "Clinical Trials – Limits on the Kind of Data that Can be Generated and Why Superiority is So Hard."
- 157. Mycoses Study Group Education and Research Consortium: 25 Jan 2022 Workshop (virtual) entitled "Novel Antifungal Therapies and Stewardship" with lecture entitled "(Regulatory) Landscape for Antifungal Drug Development."
- 158.32<sup>nd</sup> European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Lisbon, Portugal, 23-26 April 2022. Speaker in a symposium entitled "A moment to reset: Harnessing learnings to tackle antimicrobial resistance," with a lecture entitled "A moment to reset: The economics of antibiotics: The pipeline is almost empty... why?"
- 159.NIAID Virtual Workshop: Strategies for Early-Stage Programs Developing Novel Antibacterial and Antifungal Drugs, 22-23 June 2022. Keynote lecture entitled: "Strategies for Early R&D: Plumbing, Phase 3, and Durable Value.
- 160.International Course on Antibiotics and Resistance (ICARe), 15-23 Oct 2022, Annecy, France. Lecture entitled "(New) Pathways to Antibiotic Registration."
- 161.NASEM (National Academies of Science, Engineering, and Medicine) Workshop: The Impact and Control of Valley Fever, 17-18 Nov 2022. Speaker in a session entitled "Current patient management" with a talk entitled "Developing Therapies for Coccidioidomycosis: A Developer's Perspective."
- 162.7<sup>th</sup> AMR Conference, 16-17 Mar 2023 (Basel): Speaker in a session entitled "Antifungals" with a talk entitled "The Challenge of Developing New Antifungal Agents for Invasive Fungal Infections."
- 163.7<sup>th</sup> AMR Conference, 16-17 Mar 2023 (Basel): Speaker in a session entitled "Improving the chance of success of clinical trials in unmet medical need populations" with a talk entitled "Improving the chance of success of clinical trials in unmet medical need populations."
- 164.ASM-ESCMID Joint Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance (19-22 Sep 2023 (Boston). Lecture entitled "Complexities of Antifungal and Antibacterial Clinical Programs, Case Study: The example of Olorofim."
- 165.International Course on Antibiotics and Resistance (ICARe), 7-15 Oct 2023, Annecy, France. Lecture entitled "(New) Pathways to Antibiotic Registration."

- 166.10<sup>th</sup> Nikkei FT Communicable Diseases Conference: Speaker with a talk entitled "The importance of (new) antibacterial and antifungal drugs: Why don't we have the drugs we need?"
- 167.Global Coalition on Aging (GCOA) and the Infectious Disease Society of America (IDSA): 15 Feb 2024 (virtual): Discussant during a webinar entitled "AMR Preparedness Index: 2024 Progress Report."
- 168.Uppsala Antibiotic Days Conference, 28-29 May 2024, Uppsala, Sweden. Keynote speaker with talk entitled "The Economics of Antibiotic Discovery and Development."
- 169.BIO International Convention, 3-6 Jun 2024, San Diego, CA. Panelist in a program entitled "Let's Go STEDI: Moving Beyond QALYs to Understand the True Value of Antimicrobials and Vaccines."

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