

CURRICULUM VITAE

Name **John H. Powers III, M.D., F.A.C.P., F.I.D.S.A.**

Current Position Senior Medical Scientist (Physician III)
Clinical Collaborative Research Branch
Division of Clinical Research
Leidos Biomedical Research in support
of National Institute of Allergy and
Infectious Diseases
National Institutes of Health

Current Academic Positions Infectious Diseases Attending, National
Institute of Allergy and Infectious
Diseases, National Institutes of Health,
Bethesda, MD

Assistant Clinical Professor of Medicine,
University of Maryland School of
Medicine, Baltimore, MD

Associate Clinical Professor of Medicine,
George Washington University School of
Medicine, Washington, DC

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Citizenship United States of America

Wife [Redacted]
Children [Redacted]

EDUCATION

1980-84	Bachelor of Arts	University of Pennsylvania Philadelphia, PA
1984-88	Doctor of Medicine	Temple University School of Medicine Philadelphia, PA

Internship

1988-89	Intern in Medicine	Temple University Hospital Philadelphia, PA
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Residency

1989-91	Resident in Medicine	Temple University Hospital Philadelphia, PA
1991-92	Chief Resident in Internal Medicine	Temple University Hospital Philadelphia, PA

Fellowship

1992-95	Fellow in Infectious Diseases	University of Virginia Charlottesville, VA
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CERTIFICATIONS

September 1991	Diplomate	American Board of Internal Medicine Number 135621
November 1996	Diplomate	ABIM, Infectious Diseases Number 135621

LICENSURES

State of Pennsylvania	MD-043001L
Commonwealth of Virginia	0101048364
State of Delaware	C1-0004605
State of Maryland	D52271

FACULTY POSITIONS HELD

1991-92	Clinical Instructor in Internal Medicine, Temple University Hospital, Philadelphia, PA
1991-92	Residency Program Director, Germantown Hospital, Germantown, PA
1991-92	Emergency room physician, Germantown Hospital
1991-92	Emergency room physician, Medical College of Pennsylvania, Bucks County Campus
1991-94	Critical care physician on staff, Medical College of

- 1993-95 Pennsylvania, Elkins Park campus, Elkins Park, PA
House physician, Martha Jefferson Hospital
Charlottesville, VA
- 1995-97 Assistant, Department of Medicine, Section of Infectious
Diseases, Medical Center of Delaware, Wilmington,
Delaware
- 1995-97 Assistant, Department of Medicine, Section of Infectious
Diseases, St. Francis Hospital, Wilmington, Delaware
- 1995-97 Instructor in Medicine, Thomas Jefferson University
School of Medicine, Philadelphia, Pennsylvania
- 1997-99 Assistant Professor of Medicine, Division of Infectious
Diseases, Department of Medicine, University of Maryland
School of Medicine, Baltimore, Maryland
- 1997-2000 Medical Officer, Baltimore Veterans Administration Medical Center,
Division of Clinical Research, Baltimore, Maryland
- 1999-2002 Medical Officer, Division of Special Pathogen and Immunologic Drug
Products, Office of Antimicrobial Products, Center for Drug
Evaluation and Research, U.S. Food and Drug Administration
- 2002-06 Lead Medical Officer, Antimicrobial Drug Development and
Resistance Initiatives, Office of Antimicrobial Products, Center for
Drug Evaluation and Research, U.S. Food and Drug Administration
- 2000- Infectious Diseases Attending, National Institute of Allergy
Infectious Diseases, National Institutes of Health, Bethesda,
Maryland
- 2000-2011 Assistant Clinical Professor of Medicine, Division of
Infectious Diseases, Department of Medicine, University
of Maryland School of Medicine, Baltimore, Maryland
- 2000-2010 Assistant Clinical Professor of Medicine, George
Washington University School of Medicine, Washington,
DC
- 2011 - Associate Clinical Professor of Medicine, George
Washington University School of Medicine, Washington,
DC

PROFESSIONAL MEMBERSHIP

- 1984-present Phi Beta Kappa Honor Society
- 1986-present American Medical Association
- 1990-91 American College of Physicians, Associate Member
- 1990-92 Pennsylvania Medical Society
- 1991-2001 American College of Physicians, Member
- 1992-95 Virginia Infectious Disease Society
- 1992-present American Society for Microbiology
- 1994-2001 Infectious Diseases Society of America, Associate
Member
- 1995-1997 Medical Society of Delaware
- 1995-1997 New Castle County Medical Society
- 2000-present Greater Washington Infectious Diseases Society

2000-present	Federal Physicians Association
2001-2003	Infectious Diseases Society of America, Member
2002-present	American College of Physicians – American Society of Internal Medicine, Fellow
2004-present	Infectious Diseases Society of America, Fellow

HONORS, AWARDS

1984	Phi Beta Kappa Honor Society, Magna Cum Laude
1988	Graduated in top one third of medical school class
1990	Selected Chief Resident in Internal Medicine for 1991-92.
1994	Second place, University of Virginia Research Day presentations (out of 40 abstracts)
1994-95	Nominated for Dean's Teaching Award for Residents and Fellows (one of two fellows nominated out of 134 total fellows)
1995	Second place, American College of Physicians, Virginia Chapter Annual Meeting presentations (out of over 50 submitted presentations)
1995-96	International Who's Who of Professionals
1996	Outstanding Preceptor of the Year. Family Practice and Community Medicine Residency Program. Medical Center of Delaware
1996	Teacher of the Year. Department of Internal Medicine. Medical Center of Delaware
2000	Certificate of Achievement for outstanding performance in review of acute exacerbation of chronic bronchitis indication for moxifloxacin (Avelox). Division of Special Pathogens and Immunologic Drug Products.
2000	CDER Team Excellence Award for review of moxifloxacin (Avelox) application. Center for Drug Evaluation and Research.
2002	Elected as Fellow of American College of Physicians – American Society of Internal Medicine.
2002	CDER Group Recognition Award as a member of the Guidance to Industry for inhalational anthrax team
2001	FDA Award of Merit as member of the Federal Register Notice on doxycycline and penicillin G procaine group for inhalational anthrax
2003	CDER Group Recognition Award as member of the voriconazole NDA review team
2002	CVM Certificate of Appreciation for contribution and leadership on Draft Guidance Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern
2003	CDER Team Excellence Award for development of new approaches to the labeling of drugs for the treatment of infections due to antibiotic resistant pathogens
2004	FDA Award of Merit as member of the Antimicrobial Resistance Guidance Group for the Center for Veterinary Medicine

- 2005 FDA Award for Excellence in Mentoring, Antimicrobial clinical trials discussion group
- 2006 Awarded by editorial staff as one of top 5% of reviewers for the journal Clinical Infectious Diseases for excellence in peer review
- 2007 Nominee for Distinguished Clinical Teacher Award by National Institutes of Health Fellows Committee
- 2010 National Institutes of Health Directors Award for response to H1N1 influenza
- 2013 Medal of Honor, US Veteran's Affairs as member of VA Clinical Trials Evaluation group
- 2013 Medal of Honor, US Public Health Service for contributions to outcomes research

EDITORIAL TASKS

- 1996-present Reviewer, Clinical Infectious Diseases, ed. Sydney Finegold/Sherwood Gorbach
- 2000-present Reviewer, National Library of Medicine (determine inclusions of journals in PubMed citations)
- 2003 Reviewer, Antimicrobial Agents and Chemotherapy, ed. George Eliopoulos
- 2003 - present Reviewer, Journal of Clinical Microbiology
- 2003 – present Editorial board, Antimicrobial Agents and Chemotherapy, ed. George Eliopoulos
- 2004 – present Reviewer, Chest
- 2004 – present Reviewer, Clinical and Diagnostic Laboratory Immunology
- 2011 – present Reviewer, New England Journal of Medicine

COMMITTEE ACTIVITIES

- 1995-1997 Member, Antimicrobial Surveillance Subgroup of the Pharmacy and Therapeutics Committee, Medical Center of Delaware
- 1996-1997 Alternate Member, Institutional Review Board of the Medical-Dental Staff, Medical Center of Delaware
- 1997-1999 Alternate Member. Medical School Faculty Committee. University of Maryland School of Medicine
- 1999-2006 FDA ODEIV Fungal Focus Group
- 2000-2006 FDA ODEIV QT Working Group
- 2000-2006 FDA CDER-CVM Antibiotic Working Group
- 2002-2006 FDA CDER Exposure-Response Working Group
- 2002-present National Foundation for Infectious Diseases conference on antimicrobial resistance scientific program committee
- 2002-2006 Co-chair, US Federal government Interagency Task Force on Antimicrobial Resistance
- 2002-2006 Co-chair, FDA Antimicrobial Resistance Subcommittee
- 2003-2006 Advisor, Infectious Diseases Society of America (IDSA) Antimicrobial Availability Task Force

2004	Member, Centers for Disease Control and Prevention Expert Panel on Strategies for Clinical Management of Methicillin Resistant <i>Staphylococcus aureus</i> in the Community
2004-2006	Co-chair, CDER/CDRH Working group on antimicrobials and devices
2004-2007	Advisor, Clinical and Laboratory Standards Institute (CLSI) Subcommittee on Antimicrobial Susceptibility Testing
2005-present	Rapporteur, World Health Organization (WHO) working group on ranking of antimicrobial drugs according to important for human medicine
2005-present	Program Reviewer, Centers for Disease Control and Prevention Emerging Infectious Diseases and FoodNet programs
2005-2006	CDER multiplicity in clinical trials guidance working group
2005-2006	CDER non-inferiority trials guidance working group
2006 -2012	Advisor, Infectious Diseases Society of America research committee
2006-2012	Member, Infectious Disease Society of America Resistance Research Working Group
2006- present	Program Reviewer, Centers for Disease Control and Prevention GetSmart judicious use of antibiotics program
2007	Consultant, Inter-Agency Task Force on Antimicrobial Resistance in development of Public Health Action Plan to Address Antimicrobial Resistance
2008-present	Committee member, Joint Program Committee for Military Operational Medicine Research Program, Congressionally Directed Deployment Related Medical Research Program (DRMRP), Department of Defense
2009-present	Advisor, World Health Organization, Advisory Group for Integrated Surveillance of Antimicrobial Resistance (AGISAR)
2009	Ad hoc member, Department of Veterans Affairs, Cooperative Studies Scientific Evaluation Committee (CSSEC)
2010 - present	Full member, Department of Veterans Affairs, Cooperative Studies Scientific Evaluation Committee (CSSEC)
2010-present	Member, Foundation for National Institutes of Health, Biomarkers Consortium, Development of Endpoints for Skin and Pneumonia trials
2011-present	Member, SAIC Senior Leadership Advisory Group for Clinical Monitory Research Program (CMRP)
2012- present	Member, Brookings Council on Antibacterial Drug Development (BCADD), Brookings Institute
2012-present	Member, FDA-Duke Clinical Trials Transformation Initiative

PUBLICATIONS

Book Chapters

1. Powers J. Rein M. Gonococcus - *Neisseria gonorrhoeae*. In Schlossberg D, ed. Current Therapy of Infectious Disease. St. Louis: Mosby-Year Book; 1996;421-424

2. Powers J, Rein M. Gonococcus. In Kassirer JP, Green H, ed. Current Therapy in Adult Medicine. St. Louis: Mosby-Year Book; 1997.
3. Powers J. Rein M. Gonococcus - *Neisseria gonorrhoeae*. In Schlossberg D, ed. Current Therapy of Infectious Disease. 2nd edition, St. Louis: Mosby-Year Book; 2001; 507-510.
4. Powers JH. Interpreting the results of clinical trials of antimicrobials. In Mandell G, Bennett J, Dolin R, ed. Principles and Practice of Infectious Diseases 6th edition, Chapter 44, Philadelphia: Elsevier Churchill Livingstone, 2005; 619-628.
5. Powers JH, Jackson MM. Infections in special patient populations. In Mahon CR, Lehman DC, Manuselis G, ed. Textbook of Diagnostic Microbiology 3rd edition, St. Louis: Saunders Elsevier, 2007;1047-54.
6. Powers JH. Interactions between clinicians and the microbiology laboratory. In Steele-Moore L, Schwalbe R, and Goodwin AC, ed. Antimicrobial Susceptibility Testing Protocols, 2007; Chapter 17.
7. Powers JH. Interpreting the results of clinical trials of antimicrobials. In Mandell G, Bennett J, Dolin R, ed. Principles and Practice of Infectious Diseases 7th edition, Chapter 47, Philadelphia: Elsevier Churchill Livingstone, 2010; 677-698.
8. Powers, JH. Designing and interpreting clinical studies in infectious diseases. In Bennett JE, Dolin R, Blaser, MJ, ed. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases 8th edition, Chapter 52, Philadelphia: Elsevier Churchill Livingstone, 2014.

Refereed Publications

Articles

1. **Powers JH**, Buster B, Reist C, et al.: Complement independent binding of microorganisms to primate erythrocytes *in vitro* by cross-linked monoclonal antibodies via complement receptor 1. Infect Immun. 1995 Apr;63(4):1329-1335.
2. **Powers JH**, Scheld WM. Fever in neurological diseases. Infect Dis Clin North Am. 1996 Mar;10(1):45-66.
3. **Powers JH**. Counterpoint: Alternative trial designs for antifungal drugs: time to talk. Clin Infect Dis. 2001 Jul 1;33(1):107-109.
4. Colgan R, **Powers JH**. Appropriate antimicrobial prescribing: approaches that limit antibiotic resistance. Am Fam Physician 2001 Sept 15;64(6):999-1004.
5. Bennett JE, **Powers J**, dePauw B et al. Issues in the design of trials of drugs for the treatment of invasive aspergillosis. Clin Infect Dis 2003;Apr 15;36 (Suppl

- 3):S113-116.
6. Bennett JE, **Powers J**, Walsh T et al. Issues in clinical trials of empirical antifungal therapy in treating febrile neutropenic patients. *Clin Infect Dis* 2003 Apr 15;36 (Suppl 3):S117-22.
 7. Bennett JE, Kauffman C, Walsh T, DePauw B, Dismukes W, Galgiani J, Glauser M, Herbrecht R, Lee J, Pappas P, **Powers J** et al. Issues in the evaluation of diagnostic tests, use of historical controls, and merits of multicenter collaborative groups. *Clin Infect Dis* 2003 Apr 15;36 (Suppl 3):S123-127.
 8. **Powers JH**. Development of drugs for antimicrobial-resistant pathogens. *Curr Opin Infect Dis*. 2003 Dec;16(6):547-51. PMID: 14624104 .
 9. Spellberg B, **Powers JH**, Brass EP, Miller LG, Edwards JE Jr. Trends in antimicrobial drug development: implications for the future. *Clin Infect Dis*. 2004 May1;38(9):1279-86. PMID 15127341.
 10. **Powers JH**. Issues in clinical trials of prophylaxis of fungal infections. *Clin Infect Dis*. 2004 Oct 15;39 Suppl 4:S211-7. PMID: 15546120
 11. **Powers JH**. Considerations in clinical trials of combination antifungal therapies. *Clin Infect Dis*. 2004 Oct 15;39 Suppl 4:S228-35. PMID: 15546123.
 12. **Powers JH**. Antimicrobial drug development--the past, the present, and the future. *Clin Microbiol Infect*. 2004 Nov;10 Suppl 4:23-31. PMID: 15522037.
 13. DePietropaolo DL, **Powers JH**, Gill JM, Foy AJ. Diagnosis of Lyme disease. *Am Fam Physician* 2005 Jul 15;72(2):297-304,309. PMID: 16050454 and 16050455.
 14. **Powers JH**. Microbiologic surrogate endpoints in clinical trials of infectious diseases: example of acute otitis media trials. *Pharmacotherapy*. 2005 Dec;25(12 Pt 2):109S-123S. PMID: 16305280
 15. Yan SS, Pendrak ML, Foley SL, **Powers JH**. *Campylobacter* infection and Guillain-Barre syndrome: public health concerns from a microbial food safety perspective. *Clinical and Applied Immunology Reviews* 2005;5:285-305.
 16. Metlay JP, **Powers JH**, Dudley MN, Christiansen K, Finch R. Antibiotic resistance, regulation, and research. *Emerging Infectious Diseases* 2006 Feb;12(2):183-190. PMID: 16494740
 17. DePietropaolo DL, **Powers JH**, Gill JM, Foy AJ. Diagnosis of Lyme disease. *Del Med J*. 2006 Jan;78(1):11-8. PMID: 16548394
 18. **Powers JH**. Salvage therapy trials in invasive fungal disease: challenges and opportunities. *Clin Infect Dis*. 2006; Dec 1;43(11):1456-60. PMID: 17083021

19. Gorwitz RJ, Jernigan DB, **Powers JH**, Jernigan JA, and Participants in the CDC Convened Experts' Meeting on Management of MRSA in the Community. Strategies for clinical management of MRSA in the community: Summary of an experts' meeting convened by the Centers for Disease Control and Prevention. 2006. Available at http://www.cdc.gov/ncidod/dhqp/ar_mrsa_ca.html.
20. **Powers JH**. Anti-infective research and development--problems, challenges, and solutions. *Lancet Infect Dis*. 2007 Jan;7(1):74-76. PMID 17182346
21. Nelson JM, Chiller TM, **Powers JH**, Angulo FJ. Fluoroquinolone-resistant *Campylobacter* species and the withdrawal of fluoroquinolones from use in poultry: a public health success story. *Clin Infect Dis*. 2007 Apr 1;44(7):977-80. PMID: 17342653
22. **Powers JH**. Diagnosis and treatment of acute otitis media: evaluating the evidence. *Infect Dis Clin North Am*. 2007 Jun;21(2):409-26. PMID: 17561076
23. **Powers JH**. Increasing the efficiency of clinical trials of antimicrobials: the scientific basis of substantial evidence of effectiveness of drugs. *Clin Infect Dis*. 2007 Sep 1;45 Suppl 2:S153-62. PMID: 17683020
24. Patrick DL, Burke LB, **Powers JH**, Scott JA, Rock EP, Dawisha S, O'Neill R, Kennedy DL. Patient-reported outcomes to support medical product labeling claims: FDA perspective. *Value Health*. 2007 Nov-Dec;10 Suppl 2:S125-37. PMID: 17995471
25. **Powers JH**. Non-inferiority and equivalence trials: deciphering "similarity" of medical interventions. *Stat Med*. 2008 Feb 10;27(3):343-52. PMID: 18186148
26. **Powers JH**. Reassessing the design, conduct and analysis of clinical trials of therapy in community-acquired pneumonia. *Clin Infect Dis* 2008 Apr 15;46(8):1152-6. PMID: 18444849
27. Fleming TR, **Powers JH**. Issues in non-inferiority trials: the evidence in community-acquired pneumonia. *Clin Infect Dis* 2008 Dec 1;47 Suppl 3:S108-20. PMID: 18986275
28. **Powers JH**. Risk perception and inappropriate antimicrobial use: yes, it can hurt. *Clin Infect Dis*. 2009 May 15;48(10):1350-3. PMID 19361305.
29. Collignon P, **Powers JH**, Chiller TM, Aidara-Kane A, Aarestrup FM. World Health Organization ranking of antimicrobials according to their importance in human medicine: A critical step for developing risk

management strategies for the use of antimicrobials in food production animals. *Clin Infect Dis*. 2009 Jul 1;49(1):132-41. PMID 19489713.

30. **Powers JH**, Fleming TR. Design, conduct and analysis of clinical trials in disease due to methicillin-resistant *Staphylococcus aureus*. *Clin Pharmacol Ther*. 2009; Sep;86(3):244-7. PMID: 19707216.
31. **Powers JH**. Recommendations for improving the design, conduct and analysis of clinical trials in hospital-acquired pneumonia and ventilator-associated pneumonia. *Clin Infect Dis* 2010 Aug 1;51 Suppl 1:518-28. PMID: 20597667.
32. Kline-Leidy N, Wilcox T, Jones PW, Murray L, Winnette R, Howard K, Petrillo J, **Powers J**, Sethi S for the EXACT-PRO Study Group. Development of the EXAcerbations of Chronic Obstructive Pulmonary Disease Tool (EXACT) – A Patient-Reported Outcome (PRO). *Value in Health*. 2010 Dec;13(8):965-75. PMID 20659270.
32. **Powers JH**. Practice guidelines: Belief, criticism and probability. *Arch Intern Med* 2011 Jan 10;171(1):15-7. PMID 21220655.
33. Kline-Leidy N, Wilcox TK, Jones PW, Roberts L, **Powers JH**, Sethi S for the EXACT-PRO Study Group. Standardizing measurement of COPD exacerbations: Reliability and validity of a patient-reported diary. *Am J Respir Crit Care Med* 2011 Feb 1;183(3):323-329. PMID: 20813886
34. Laxminarayan R. **Powers JH**. Antibacterial R&D incentives. *Nat Rev Drug Discov*. 2011 Sep 30;10(10):727-8. PMID 21959280.
35. Lifson AR, Krantz EM, Grambsch PL, Macalino GE, Crum-Cianflone NF, Ganesan A, Okulicz JF, Eaton A, **Powers JH**, Eberly LE, Agan BK; Infectious Disease Clinical Research Program HIV/STI Working Group. Clinical, demographic, and laboratory parameters at HAART initiation associated with decreased post-HAART survival in a US military prospective cohort. *AIDS Res Ther*. 2012 Feb 10;9(1):4. PMID 22339893.
36. **Powers JH**. Asking the right question: morbidity, mortality, and measuring what's important in unbiased evaluations of antimicrobials. *Clin Infect Dis*. 2012 Jun;54(12):1710-3. PMID 22467671.
37. Fleming TR, **Powers JH**. Biomarkers and surrogate endpoints in clinical trials. *Stat Med*. 2012 Nov 10;31(25):2973-84. PMID 22711298.

38. Talbot GH, **Powers JH**, Fleming TR, Siuciak JA, Bradley J, Boucher H; CABP-ABSSSI Project Team. Progress of developing endpoints for registrational clinical trials of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections: update from the Biomarkers Consortium of the Foundation for the National Institutes of Health. *Clin Infect Dis* 2012 Oct;55(8):1114-21. PMID 22744885.
39. Wyrwich KW, Yu H, Sato R, Strutton D, **Powers JH**. Community-acquired pneumonia: symptoms and burden of illness at diagnosis among US adults aged 50 years and older. *Patient*. 2013 Apr 3. [Epub ahead of print] PMID: 23549929.
40. **Powers JH**, Fleming TR. Non-inferiority trials: clinical understandings and misunderstandings. *Clin Investig (Lon)*. 2013 Mar 1;3(3):215-18.
41. Ames N, Peng C, **Powers JH**, Leidy NK, Miller-Davis C, Rosenberg A, Wallen GR. Beyond intuition: Patient fever symptom experience. *J Pain Symptom Manage*. 2013 Jun 4 S0885-3924(13)00229-7.10.1016/j.jpainsymman.2013.02.012. [Epub ahead of print] PMID: 23742739
42. Hartz A, He T, Wallace R, Powers J. Comparing hormone replacement therapy effects in two RCTs and two large observational studies that used similar methods for comprehensive data collection and outcome assessment. *BMJ Open* 2013 Jul 15(7). pii: e002556. doi: 10.1136/bmjopen-2013-002556. PMID 23861441
43. Outtersson K, **Powers JH**, Seoane-Vazquez E, Rodriguez-Monguio R, Kesselheim A. Approval and withdrawal of new antibiotics and other anti-infectives in the US> 1980-2009. *J Law Med Ethics* 2013 Sep;41(3):689-96. PMID: 24088160.
44. Follmann D, Brittain E, Powers JH. Discordant minimum inhibitory concentration analysis: a new path to licensure for anti-infective drugs. *Clin Trials* 2013;10(6):876-85. PMID 24287133
45. Herrick JA, Lederman RJ, Sullivan B, Powers JH, Palmore TN. Brucella arteritis: clinical manifestations, treatment and prognosis. *Lancet Infect Dis* 2014 Jan 27. pii: S1473-3099(13)70270-6. doi: 10.1016/S1473-3099(13)70270-6. [Epub 2014 Jan 28] PMID: 24480149

Letters

1. **Powers JH**, Dixon CA, Goldberger MJ. Voriconazole versus liposomal

- amphotericin B in patients with neutropenia and persistent fever. *N Engl J Med* 2002 Jan 24;346(4):289-90. PMID 11807157.
2. **Powers JH**, Ross DB, Brittain E, Albrecht E, Goldberger MJ. The U.S. Food and Drug Administration and noninferiority margins in clinical trials of antimicrobial agents. *Clin Infect Dis* 2002 Mar 15;34(6):879-81. PMID 1180875.
 3. **Powers JH**, Dixon CA, Goldberger MJ. Decisions about voriconazole versus liposomal amphotericin B. *N Engl J Med* 2002 May 9;346(19):1499.
 4. Johann-Liang R, Zalkikar J, **Powers JH**. Correlation between bacteriologic and clinical endpoints in trial of acute otitis media. *Pediatr Infect Dis J* 2003 Oct;22(10):936-7. PMID 14551499.
 5. **Powers JH**, Albrecht R. Lipid amphotericin formulations as comparators in clinical trials. *Clin Infect Dis* 2004 Jan;38(2):305-6. PMID 14699471.
 6. **Powers JH**, Johann-Liang R. Tubes and ear infections. *Pediatrics*. 2004Jan;113(1 Pt1):178-9. PMID 14702480.
 7. **Powers JH**, Cooper CK. Evaluating combination therapy in community-acquired pneumonia. *Chest* 2004 Jan;125(1):353. PMID 14718472.
 8. **Powers JH**, Higgins KM. Itraconazole versus fluconazole for antifungal prophylaxis. *Ann Intern Med*. 2004 Apr 6;140(7):580. PMID: 15068992
 9. **Powers JH**, Ross DB, Lin D, Soreth J. Linezolid and vancomycin for methicillin-resistant *Staphylococcus aureus* nosocomial pneumonia: the subtleties of subgroup analyses. *Chest*. 2004 Jul;126(1):314-5. PMID 15249482.
 10. **Powers JH**, Zalkikar J, Johann-Liang R. Correlation between bacteriologic eradication and clinical cure in acute otitis media. *Pediatr Infect Dis J*. 2004 Oct;23(10):976. PMID: 15602210.
 11. **Powers JH**. Empirical antifungal therapy in febrile neutropenic patients: caution about composite end points and the perils of P values. *Clin Infect Dis*. 2004 Dec 1;39(11):1738-9. PMID: 15578387.
 12. Marcus KA, Johann-Liang R, **Powers JH**. Ribavirin trials and hantavirus--what we should not conclude. *Clin Infect Dis*. 2005 May 15;40(10):1550-1. PMID: 15844085.
 13. **Powers JH**, Lin D, Ross D. FDA evaluation of antimicrobials: subgroup analysis. *Chest*. 2005 Jun;127(6):2298-9. PMID: 15947370.

14. **Powers JH**, Cooper CK, Lin D, Ross DB. Sample size and the ethics of non-inferiority trials. *Lancet*. 2005 Jul 2;366(9479):24-5. PMID: 15993221.
15. Kraus CN, Zalkikar J, **Powers JH**. Levofloxacin and macrolides for treatment of legionnaires disease: multiple comparisons give few answers. *Clin Infect Dis*. 2005 Aug 1;41(3):416. PMID: 16007549.
16. Outterson MK, **Powers JH**, Gould IM, Kesselheim AS. Questions about the 10 x '20 initiative. *Clin Infect Dis* 2010 Sep 15; 51(6):751-2. PMID: 20731566.
17. Decker BK, **Powers JH**. Using the Rate of Bacterial Clearance Determined by Real-Time Polymerase Chain Reaction to Evaluate Antibiotic Effectiveness in *Acinetobacter baumannii* Bacteremia. *Crit Care Med*. 2013 May;41(5):e47. PMID: 23591227
18. Tamma PD, **Powers JH**. Do patient data really support the CLSI recommendation for lowering third-generation cephalosporin interpretive breakpoints? *Clin Infect Dis*. 2013 May 8. PMID: 23658433
19. Hataye JM, Palmore TN, Powers JH. Duodenal infusion of feces for recurrent *Clostridium difficile*. *N Engl J Med* 2013 May 30;368(22):2143-4. PMID: 23742739.

Non-Refereed Publications

Articles

1. The HIV Program at the University of Virginia Medical Center. A Practical Guide to The Management of HIV Infection. Charlottesville: University of Virginia Press, 1995
2. **Powers J**. Scheld WM. Cefepime: a new β -lactamase resistant broad spectrum cephalosporin. *Resident and Staff Physician*, 1996; 42(6):46-55.
3. **Powers J**. Scheld WM. Human ehrlichioses: the newest tick-borne diseases. *Contemporary Internal Medicine*, 1996; 8 (7): 68-79.

Abstracts

1. **Powers J**, Zachary M, Reist C, et al.: Complement independent binding of herpes simplex virus-1 capsid to human erythrocytes via complement receptor 1. Abstracts from the 33rd Interscience Conference on Antimicrobial Agents and Chemotherapy, *Am Soc Microbiol* p.206, 1993.

2. Taylor RP, Reist CJ, Liang HY, Muzykantov V, Zachary M, Scheld WM, **Powers J**, Buster B. Heteropolymer mediated binding of target antigens to primate erythrocytes via CRT. *In vitro* analyses. Molecular Immunology Abstracts of the XV International Complement Workshop, Kyoto, Japan. 1993.
3. **Powers JH**, Winston DC, Lopes MPS, Hazen KC. Central nervous system infection with *Trichoderma viride*. Abstracts from the 34th Interscience Conference on Antimicrobial Agents and Chemotherapy, Am Soc Microbiol, Late Breaker Session, 1994.
4. Bogaev RC, **Powers JH**. Adult Reye's syndrome. Abstracts from the Annual Meeting of the Virginia Chapter of the American College of Physicians in Virginia Medical Quarterly. 1995; 22(2): p.94.
5. Mattes KA, Buster BL, **Powers JH**, Scheld WM. Monoclonal antibody-mediated complement independent binding of human tumor necrosis factor- α to primate erythrocytes via complement receptor-1. Abstracts from the 35th Interscience Conference on Antimicrobial Agents and Chemotherapy, Am Soc Microbiol, p. 174, 1995.
6. Brink WC, **Powers JH**. Legionella pericarditis. Abstracts from the Annual Meeting of the Virginia Chapter of the American College of Physicians in Virginia Medical Quarterly. 1996.
7. Steele-Moore L, Schneider B, **Powers J**, Holloway WJ. *In vitro* activity of voriconazole (UK109,406) against clinical isolates of *Candida lusitanae*. Trends in Fungal Infections, Barcelona, Spain. Poster 84. November 6, 1997.
8. Navarro E, Dixon C, **Powers JH**. Evaluating efficacy of systemic antifungals for esophageal candidiasis: a comparison of clinical trial designs. Focus on Fungal Infections 14, New Orleans, LA. Abstract 17. March 24-26, 2004.
9. Punderson JW, Claycamp HG, Flynn WT, Gilbert JM, Hooberman B, Lampe KER, Mulinde J, **Powers J**, Sheldon A, Tollefson L, Walker RD, Yan SS. Risk assessment development at FDA through inter-Center collaboration: development of a microbial food safety guidance for the Center for Veterinary Medicine. FDA Science Forum, Washington, DC. May 13, 2004.
10. Johann-Liang R, Zalkikar J, **Powers JH**. Lack of concordance between clinical and microbiological outcomes in double-tympanocentesis trials in children with acute bacterial otitis media. Abstracts from the 42nd Annual Meeting of the Infectious Diseases Society of America. Boston, MA. Abstract 272, p. 85. September 30, 2004.
11. **Powers JH**, Moncada V, Johann-Liang R. Disease severity assessment in community-acquired pneumonia: comparison of the PORT criteria with the original and revised ATS criteria. Abstracts from the 44th Interscience Conference on Antimicrobial Agents and Chemotherapy, Am Soc Microbiol.

Washington, DC. Abstract L-655. October 31, 2004.

12. Cooper CK, Rochester G, Komo S, **Powers JH**. Misclassification bias in clinicians' assessments (CA) of patient outcomes and patient symptoms (PS) in antimicrobial therapy of acute exacerbations of chronic bronchitis (AECB). 45th Interscience Conference on Antimicrobial Agents and Chemotherapy, Am Soc Microbiol. San Francisco, CA. 2005.
13. Leidy NK, Burke LB, **Powers JH**, Howard KA, Petrillo JM, Wilcox TK. The EXACT-PRO initiative: development of a standardized measure for evaluating exacerbations of chronic obstructive pulmonary disease. American Thoracic Society International Conference, Toronto, Canada. Abstract #D44, page A139. May 18, 2008.
14. Leidy NK, Wilcox TK, Burke LB, Howard KA, Petrillo JM, Jones PW, Sethi S, **Powers JH**. Reliability and validity of the Exacerbations of Chronic Pulmonary Disease tool (EXACT): a new outcome measure for evaluating exacerbations of COPD. American Thoracic Society International Conference, Toronto, Canada. Abstract #D45, page A139. May 18, 2008.
15. Rodriguez-Monguio R, Seoane Vazquez E, Outtersson K, **Powers JH**. Analysis of antimicrobial NMEs and BLAs Approved in the U.S. (1980-2009). Abstract: American Public Health Association, 138th Annual Meeting & Exposition (November 6-10, 2010).
16. Wyrwich K, Yu H, Sato R, Strutton D, **Powers J**. Return to full productivity in adults 50 years and older after an episode of community-acquired pneumonia. Abstracts from the 49th Annual Meeting of the Infectious Diseases Society of America, Boston, MA. Abstract 365, p. 65. October 22, 2011.
17. **Powers JH**, DeAnda C, Casseday C, Das A, Fang E, Prokocimer P. Reliability and reproducibility of lesion size measurements in patients with skin abscesses or cellulitis. IDWeek 2013, San Francisco, CA. Abstract 1342, p. 94. October 3, 2013.
18. Prokocimer P, Fang E, DeAnda C, Casseday C, **Powers JH**, Das A. Impact of different methods of lesion size measurement on outcomes in acute bacterial skin and skin structure infection (ABSSSI) clinical trials. IDWeek 2013, San Francisco, CA. Abstract 813, p. 88. October 3, 2013.
19. DeAnda C, Fang E, Das A, **Powers JH**, Prokocimer P. Association of lesion size changes and pain acute bacterial skin and skin structure infection (ABSSSI) clinical trials: assessing how patients feel. IDWeek 2013, San Francisco, CA. Abstract 1341, p. 94 October 2, 2013.
20. **Powers JH**, Stringer SM, Clifford S, Kim K, Arnold J, Schofield C, Danaher P, Stepp N, Brown B, Kronmann K, Burgess T, Fairchok M, Ridore M, Millar E, Lourdes-Guerrero M, Ruiz-Palacios GM, Hernandez A,

Rodriguez-Zulueta AP, Galindo-Frego A, Rosenberg A, Kline-Leidy N. Development of patient-reported outcome instrument FLU-PRO to standardize and quantify symptoms of influenza. IDWeek 2013, San Francisco, CA. Abstract 902, p. 90. October 2, 2013.

CDER COURSES

New Employee Orientation	February 16, 1999
CDER Pharmacodynamics Workshop	March 1, 1999
Introduction to Drug Law (sponsored by Federal Drug Law Institute)	November 4-5, 1999
Pharmacokinetics and Pharmacodynamics for CDER Reviewers	February 17- Mar 23, 2000
Topics in Clinical Trials	March 31 – June 30, 2000
New Reviewer's Workshop	May 18-26, 2000
Technical Writing for Reviewers	June 5-7, 2000
Career Development Workshop	January 17, 2001
Basic Statistics	January 31-March 21, 2001
FAME Leadership Course	April 26-30, 2004

OUTSIDE COURSES

Training Course in Hospital Epidemiology (sponsored by Society for Healthcare Epidemiology of America and Centers for Disease Control)	March 1-4, 1999
Drug Development in Anti-Infectives (sponsored by Pharmaceutical and Education Research Institute)	March 22-24, 1999

OIT COMPUTER COURSES

DFS Training	February 25, 1999
Introduction to MS Access	February 25, 1999
JMP Training	January 13,18,25, 1999
PDF training	January 21, 1999
NEST Training	March 13, 2000
NEDAT Training	March 14, 2000
AERS training	August 18, 2000

CDER LIBRARY COURSES

Introduction to PubMed	December 16, 1999
Introduction to DialogSelect	January 11, 2000

Search Journals course	February 3, 2000
Current Contents tutorial	March 10, 2000
Introduction to New PubMed	April 25, 2000

TEACHING RESPONSIBILITIES

1995-1997	Preceptor for Infectious Diseases rotations: 1) Internal Medicine 2) Family Medicine 3) Thomas Jefferson University School of Medicine students.
1995-1997	Instructor for Introduction to Clinical Medicine Course, Thomas Jefferson University School of Medicine students
1997-present	discussion leader for Group Sessions in Microbiology, University of Maryland second year medical students
1997- present	examiner for Junior Oral Examinations for Medicine rotation, University of Maryland School of Medicine third year students
1997-present	instructor for Infectious Disease fellows, University of Maryland fellowship program
2000-present	instructor for infectious diseases fellows, National Institutes of Health, Bethesda, Maryland
2000-present	instructor for medical students and residents, George Washington University School of Medicine, Washington, DC
2004 – 2006	developed and teach clinical trials design and analysis discussion series for FDA reviewers in Office of Antimicrobial Products
2005- 2007	instructor in Introduction to Design, Conduct and Review of Clinical Trials course for reviewers in Center for Drug Evaluation and Research, U.S. Food and Drug Administration
2006- present	instructor, Clinical Investigator Training Program (CITP), Harvard-Beth Israel Deaconess Medical Center

MAJOR INVITED SPEECHES, GRAND ROUNDS

Update on Acute Bacterial Meningitis. Department of Medicine Grand Rounds, Medical Center of Delaware, October 5, 1995.

Bacterial Resistance: Impact on Clinical Practice. Department of Internal Medicine Residency Core Lecture, October 10, 1995.

Urinary Tract Infections: Diagnosis and Treatment. Department of Family Practice Residency Core Lecture, Medical Center of Delaware, October 19, 1995.

New Developments in Treatment of Acute Bacterial Meningitis. Department of Neurology Grand Rounds, Medical Center of Delaware, November 9, 1995.

Cephalosporins in Clinical Practice. Department of Family Practice Residency Core Lecture, Medical Center of Delaware, November 13, 1995.

The "Flesh Eating Bacteria" of Necrotizing Fasciitis. Division of Infectious Diseases Conference, Medical Center of Delaware, December 6, 1995.

The Microbiology Laboratory in Clinical Practice. Infectious Diseases Research Laboratory, Medical Center of Delaware, March 18, 1996.

Treatment Issues in Candidemia. Division of Infectious Diseases Conference, Medical Center of Delaware, March 20, 1996.

Vancomycin in the Therapy of Neutropenic Febrile Cancer Patients: The Possible Impact on the Spread of Vancomycin Resistant Enterococci. Hematology-Oncology Conference, Medical Center of Delaware, March 28, 1996.

Treatment of Respiratory Tract Infections in the Outpatient Setting. Dover Air Force Base Hospital, Dover Delaware, April 16, 1996.

Choice of Antifungal Agents in Candidemia. St. Francis Hospital Family Practice Residency Lecture. Wilmington, Delaware, May 8, 1996.

Quinolone Use in Clinical Practice: Case Studies. McNeil Pharmaceutical Company Preceptorship Course. Newark, Delaware. May 29, 1996.

Therapy of Deep Seated Fungal Infections. Union Hospital. Elkton, Maryland. June 11, 1996.

Antiretroviral Drugs in the Treatment of HIV Infection. Department of Internal Medicine Residency Core Lecture. Medical Center of Delaware, June 11, 1996.

Antiretroviral Drugs in Clinical Practice. Department of Family Medicine Residency Lecture, Medical Center of Delaware, June 18, 1996.

Infections in the Intensive Care Unit. Milford Hospital, Milford, Delaware. June 20, 1996.

Infectious Diseases in Emergency Medicine: Case Studies. Department of Emergency Medicine, Medical Center of Delaware, June 25, 1996.

Central nervous system infections. Medical Student Core Lecture for Thomas Jefferson School of Medicine students, Medical Center of Delaware, July 16, 1996.

Case studies in antibiotic usage. Department of Family Medicine Residency Lecture, Medical Center of Delaware, July 26, 1996.

Fever in neurologic diseases. Department of Emergency Medicine Grand Rounds. Medical Center of Delaware. August 20, 1997.

Appropriate use of antibiotics in the outpatient setting. Milford Hospital Medicine Symposium. Milford, Delaware October 18, 1997.

Use of HIV viral load in clinical practice. Mercy Hospital Grand Rounds. Baltimore, MD. November 26, 1997.

Recognition of skin and soft tissue infections; superficial to deep. Southern Maryland Hospital Grand Rounds. Clinton, MD. February 4, 1998

Diagnosis and treatment of nosocomial pneumonia. Central Pennsylvania Infectious Disease Symposium. Hershey, PA. February 21, 1998

Pharmacokinetics and pharmacodynamics of antimicrobial agents. Christiana Care Health System Infectious Disease Grand Rounds. Newark, DE. March 18, 1998.

Endocarditis. Face of a changing disease. Rehobeth Beach Eighth Annual Cardiovascular Symposium. Beebe Hospital and Medical Society of Delaware. Rehobeth Beach, Delaware. July 26, 1998.

Diabetic foot infections. Diagnosis and treatment. Perrypoint Veteran's Administration Hospital Grand Rounds. July 29, 1998.

Community acquired pneumonia. Impact of resistant pathogens on therapy? Washington Veteran's Administration Hospital Pulmonary Division. Washington, DC. September 18, 1998.

Making sense of the new quinolones. Holy Cross Hospital Grand Rounds. Silver Spring, MD. October 5, 1998.

Appropriate uses of quinolones. York Hospital Department of Medicine and Family Practice Grand Rounds. York, PA. October 15, 1998.

Dosing of antibiotics. What we know and where we are going. Maryland Society of Hospital Pharmacists 33rd Annual Meeting. Deep Creek, MD. October 18, 1998.

Post-Surgical Infections. Mercy Hospital Surgical Grand Rounds. Baltimore, MD. November 11, 1998.

Appropriate Use of Antibiotics. National Institutes of Health Weekly Conference.

Bethesda, Maryland. January 31, 2000.

Pharmacodynamics and Antibiotics. National Institutes of Health Grand Rounds. Bethesda, Maryland. February 18, 2000.

Issues in Infection Control. Federated Ambulatory Surgeons Association. Washington, DC. May 5, 2000.

Clinical Trials Issues in Acute Exacerbations of Chronic Bronchitis. Pharmaceutical Education and Research Institute Course on Developing Antimicrobials. Arlington, VA. June 12, 2001.

Clinical Trials Issues in Uncomplicated and Complicated Urinary Tract Infections. Pharmaceutical Education and Research Institute Course on Developing Antimicrobials. Arlington, VA. June 12, 2001.
Issues in evaluating clinical trials. National Institutes of Health Grand Rounds. Bethesda, Maryland. March 1, 2002.

INTERNATIONAL PRESENTATIONS

“Issues in Drug Safety” and “Issues in Clinical Trial Design for Antibacterial Agents”. Clinical Trials Seminar. Medical Professionals Alliance. Taipei, Taiwan. October 25-26, 2000.

Alternative Trial Designs for Anti-Fungal Agents: The FDA Response. Focus on Fungal Infections 11th Annual Meeting. Washington, DC. March 16, 2001.

Issues in clinical trial design in antifungal agents. John E. Bennett Forum on Deep Mycoses Study Design 1st Annual Meeting. New York, New York. January 26-27, 2002.

Long term effects of ciprofloxacin in the treatment of anthrax. Anthrax Symposium sponsored by Physician’s Research Network. Houston, Texas. March 23, 2002.

Clinical trials of antimicrobial agents: a regulatory perspective. International Conference on Antimicrobial Agents and Chemotherapy (ICAAC). San Diego, CA. September, 2002.

Issues in clinical trial design for antifungal prophylaxis. John E. Bennett Forum on Deep Mycoses Study Design 2nd Annual Meeting. New York, New York. February 8-9, 2003.

Issues in clinical trial design of antifungal combination therapies. John E. Bennett Forum on Deep Mycoses Study Design 2nd Annual Meeting. New York, New York. February 8-9, 2003.

Multi-drug resistance patterns and drug development for *Staphylococcus aureus* infections. National Antimicrobial Resistance in *Staphylococcus aureus* (NARSA)

meeting. San Antonio, Texas. March 6, 2003.

Drug development for antifungal agents: a regulatory perspective. Focus on Fungal Infections 13th Annual Meeting. Maui, Hawaii. March 21, 2003.

Drug development for antimicrobial resistant pathogens. Harold Neu Infectious Diseases Conference. San Francisco, CA. April 25, 2003.

Clinical trials of antifungal therapy: a regulatory perspective. International Society for Animal and Human Mycology (ISHAM). San Antonio, Texas. May 27, 2003.

Implications of surveillance of resistant pathogens for antimicrobial drug development. National Foundation for Infectious Diseases (NFID) Annual Conference on Antimicrobial Resistance. Bethesda, MD. June 23, 2003.

Drug development for antimicrobial resistant pathogens. National Foundation for Infectious Diseases (NFID) Annual Conference on Antimicrobial Resistance. Bethesda, MD. June 24, 2003.

Regulatory issues in clinical trial design of antimicrobial agents. Multidisciplinary Alliance Against Device Related Infections (MADRI). San Antonio, TX. August 9, 2003.

Facilitating antimicrobial drug development: a regulatory perspective. International Conference on Antimicrobial Agents and Chemotherapy (ICAAC). Chicago, IL. September 15, 2003.

FDA PRESENTATIONS

CDER Quality Assurance Pre-decisional meeting for gemifloxacin. Rockville, MD. November 15, 2000.

CDER Antiviral Drugs Advisory Committee, NDA 21-266, Vfend (voriconazole) tablets and NDA 21-267, Vfend (voriconazole) for infusion. October 4, 2001.

Empiric antifungal therapy of febrile neutropenic patients – Study 603.

<http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3792t2.htm>.

CDER Anti-Infective Drugs Advisory Committee. Proposed approaches for selection of non-inferiority margins (deltas) in clinical trials of antimicrobial agents. Gaithersburg, MD. February 19, 2002. Issues in selection of deltas in clinical trials of acute bacterial meningitis and hospital-acquired pneumonia.

<http://www.fda.gov/ohrms/dockets/ac/02/agenda/3837a1.htm>.

CDER Anti-Infective Drugs Advisory Committee. Issues in clinical trials of acute otitis media. Gaithersburg, MD. July 11, 2002. Overview of guidance development.

<http://www.fda.gov/ohrms/dockets/ac/02/slides/3875s2.htm>

Center for Veterinary Medicine open public meeting. Evaluating the safety of new

antimicrobial drugs in animals. Gaithersburg, MD. October, 2002. Ranking of antimicrobial drugs according to importance in human medicine.

IDSA/PhRMA/FDA Working Group on Drug Development. Rockville, MD. November 19-20, 2002. Issues in selection of deltas in non-inferiority trials. <http://www.fda.gov/cder/present/idsaphrma/>

CDER Anti-Infective Drugs Advisory Committee, NDA 21-244 Ketek (telithromycin). Gaithersburg, MD. January 8, 2003. Macrolide-resistant *Streptococcus pneumoniae*: What is the public health impact? <http://www.fda.gov/ohrms/dockets/ac/03/slides/3919s1.htm>

CDER Anti-Infective Drugs Advisory Committee. Evaluating the safety of antimicrobial new animal drugs with regard to effects on bacteria of human health concern. Gaithersburg, MD. January 9, 2003. Ranking of antimicrobial drugs according to importance in human medicine. <http://www.fda.gov/ohrms/dockets/ac/03/slides/3919s2.htm>

CDER Anti-Infective Drugs Advisory Committee. NDA 21-158 Factive (gemifloxacin). Gaithersburg, MD. March 4, 2003. Antimicrobial resistance in *Streptococcus pneumoniae* – implications for prescription drug labeling. <http://www.fda.gov/ohrms/dockets/ac/03/slides/3931s1.htm>

CDER Anti-Infective Drugs Advisory Committee. Drug development for antimicrobial resistant pathogens. Gaithersburg, MD. March 5, 2003. Listing antimicrobial resistant pathogens of public health importance – implications for drug development. <http://www.fda.gov/ohrms/dockets/ac/03/slides/3931s2.htm>

FDA/Bacterial and Mycoses Study Group (BAMSG) Workshop. Clinical trials in combination antifungal therapy: a regulatory perspective. Bethesda, MD. September 4, 2003.

CDER Anti-Infective Drugs Advisory Committee. Closed session. Microbiological surrogate markers in clinical trials of infectious diseases. Gaithersburg, MD. October 28, 2003.

CDER Anti-Infective Drugs Advisory Committee. Clinical trial design in acute bacterial sinusitis. Gaithersburg, MD. October 29, 2003. Clinical trial design in acute bacterial sinusitis: considerations for future guidance. <http://www.fda.gov/ohrms/dockets/ac/03/slides/3997s2.htm>

CVM Veterinary Medicines Advisory Committee. Risk assessment for tulathromycin. Gaithersburg, MD. October 14, 2004. Use of macrolides in human medicine. <http://www.fda.gov/ohrms/dockets/ac/cvm04.html#VeterinaryMedicine>

CDER Anti-Infective Drugs Advisory Committee. Discussion of issues related to

clinical trial design and analysis in studying bacteremia due to *Staphylococcus aureus* and catheter-related bacteremia. Gaithersburg, MD. Clinical trial considerations in primary bacteremia due to *Staphylococcus aureus*. October 14, 2004.

<http://www.fda.gov/ohrms/dockets/ac/04/slides/2004-4077s1.htm>

CDER Non-prescription Drugs Advisory Committee. Microbiological surrogate endpoints in clinical trials of infectious diseases: implications for study of topical antiseptics. Gaithersburg, MD. March 23, 2005.

CDER regulatory briefing. Clinical trials design issues in acute exacerbations of chronic bronchitis. Rockville, MD. Systematic review of placebo-controlled trials in acute exacerbations of chronic bronchitis. July 22, 2005.

TEACHING

CLINICAL SCIENCES

- | | |
|---------------|--|
| 1995-1997 | Preceptor (12 months/year) - Infectious Diseases elective rotation attending rounds
Christiana Care Health System, residents and 4th year medicine students |
| 1995-1997 | inpatient teaching attending for Family Practice Residency Program. Christiana Care Health System |
| 1995-1997 | Instructor for Introduction to Clinical Medicine Course, Thomas Jefferson University School of Medicine students |
| 1997- present | discussion leader for Group Sessions in Microbiology, University of Maryland second year medical students |
| 1997- 1999 | examiner for Junior Oral Examinations for Medicine rotation, University of Maryland School of Medicine third year students |
| 1997- 2006 | instructor for Infectious Disease fellows, University of Maryland fellowship program |
| 1997- 1999 | preceptor for morning report. Internal Medicine residency program. University of Maryland Hospital |
| 1998-2006 | lecturer for microbiology and pharmacology core curriculum course for second year medical students. University of Maryland School of Medicine |
| 2000-present | infectious diseases clinic and inpatient attending, National Institutes of Health, Bethesda, Maryland |

- 2000-present instructor for medical students and residents, George Washington School of Medicine, Washington, DC
- 2006-present instructor, Harvard/Beth Israel Deaconess Clinical Investigator Training Program (CITP)
- 2007- present instructor, Uniformed Services University(USU) Introduction to Clinical Research courses
- 2009- present instructor, National Institutes of Health (NIH) Introduction to Principles and Practices of Clinical Research (IPPCR) course

CLINICAL RESEARCH

(co-investigator in the following studies, funding levels not available)

Open, multicenter randomized research study of itraconazole vs. amphotericin B for the treatment of invasive aspergillosis: MSG #21. NIAID Mycoses Study Group/ Janssen Research Foundation.

A multicenter, randomized prospective open study of once daily ceftriaxone alone for 4 weeks vs. once daily ceftriaxone plus gentamicin for 2 weeks for subacute bacterial endocarditis with option for home therapy in either arm. Duke University/ Roche Labs.

Azithromycin in the treatment of hospitalized patients with community acquired pneumonia. A multicenter open comparative trial employing cefuroxime as a comparative agent. Pfizer Labs.

An open, comparative, multi-centered study of fluconazole versus fluconazole plus amphotericin B in the treatment of candidemia and its consequences in non-neutropenic patients. MSG #33. NIAID Mycoses Study Group/ Pfizer Labs.

A randomized, multicenter, double-blind, double-dummy trial comparing intravenous CP-116,517 followed by oral CP-99, 219 with intravenous ciprofloxacin for the treatment of nosocomial pneumonia. Pfizer Labs.

A randomized, double blind, comparative trial of AmBisome® (liposomal amphotericin B) vs. amphotericin B in the empiric treatment of febrile neutropenic patients. Protocol 94-0-002. Fujisawa Inc., U.S.A.

Open label single emergency use protocol of amphotericin B lipid complex (Abelcet®) in patients with life-threatening fungal infection. Protocol #O1A08. The Liposome Company.

Study of the treatment of infections due to vancomycin-resistant *Enterococcus faecium* (V.R.E.F.) with Synercid® (quinupristin/dalfopristin, RP 57669/RP54476).

Protocol JRV 301 Rhone Poulenc Rorer.

A phase III randomized multicenter comparative study of Synercid® (quinupristin/dalfopristin, RP57669/RP54476) vs. standard therapy in the treatment of gram-positive skin and skin-structure infections. Protocol JRV 304. Rhone Poulenc Rorer.

A phase III, randomized, double blind, multicenter study of Synercid® (quinupristin/dalfopristin, RP57669/RP54476) vs. the combination of ceftriaxone plus erythromycin in the treatment of acute community-acquired pneumonia Protocol JRV 303. Rhone Poulenc Rorer.

Evaluation of the protective efficacy, safety, and immunogenicity of a recombinant DNA expressed protein vaccine for Lyme disease in healthy volunteers. Protocol #215274/008. Smith Kline Beecham.

Prospective, double blind, placebo controlled, randomized, multicenter, North American study of the safety and efficacy of murine monoclonal antibody to tumor necrosis factor (TNF mAb) for the treatment of patients with septic shock; Norasept II. Bayer, Inc.

Randomized placebo controlled trial of anti-endotoxin monoclonal antibody E5 in patients with severe gram-negative sepsis. Protocol 92-S-2500. Pfizer, Inc.

Azithromycin in the treatment of patients with *Legionella* pneumonia requiring hospitalization: a multicenter open trail employing intravenous followed by oral administration of azithromycin. Protocol 94-CE33-0649. Pfizer, Inc.

An open, randomized comparative multicenter study of the efficacy, safety, and toleration of voriconazole versus amphotericin B in the treatment of acute invasive aspergillosis in immunocompromised patients. Protocol 150-602. Pfizer, Inc.

Compassionate use of Ambisome® for treatment of invasive fungal infections in patients intolerant to or with disease unresponsive to standard antifungal therapy. Protocol 95-0-010. Fujisawa USA, Inc.

A protocol designed to evaluate the safety and efficacy of multi-drug combination antiretroviral therapy for the treatment of HIV-1 infection in antiretroviral naive patients with detectable HIV-1 RNA and CD4+ counts >500cells/mm³. Protocol ICC 003. Bristol Myers Squibb, Glaxo Wellcome, Pharmacia, and Upjohn.

A double-blind placebo controlled study to assess the safety, tolerability and antiretroviral activity of DMP 266 alone and in combination with open-label indinavir in HIV-infected patients. Protocol DMP266- 003. DuPont Merck.

A multicenter, double-blind, phase III, adjuvant-controlled study of the effect of 10 units of HIV-1 immunogen compared to IFA alone every 12 weeks on AIDS-free survival in subjects with HIV infection and CD4 lymphocytes between 300 and 549

cells/ μ l regardless of concomitant HIV therapies. Protocol 806. The Immune Response Corporation.

A double-blind, placebo-controlled study to assess the safety, tolerability, and antiretroviral activity of DMP 266 in combination with open-label zidovudine (ZDV) and lamivudine (3TC) in HIV-infected patients. Protocol DMP 266-004. DuPont Merck.

An international, double-blind, randomized, phase III study to evaluate the tolerance, safety, and effectiveness of Viramune® (nevirapine) in preventing clinical AIDS progression events or death when used in combination with lamivudine (3TC) and stable (>four weeks) background nucleoside therapy. Protocol 1100.1090. Boehringer Ingelheim.

An open, randomized, comparative, multicenter study of the efficacy, safety, and toleration of voriconazole versus amphotericin B followed by other licensed antifungal therapy in the treatment of acute invasive aspergillosis in immunocompromised patients. Protocol 96CE39-0685 (150-602). Pfizer, Inc.

The safety and efficacy of cefditoren vs. cefpodoxime in the treatment of community acquired pneumonia.

A prospective, multicenter, double-blind, randomized study of MK-0826 vs. ceftriaxone in the treatment of complicated urinary tract infections. Merck and Co., Inc.

A prospective, multicenter, double-blind, comparative study of MK-0826 vs. piperacillin-tazobactam in the treatment of complicated skin and skin structure infections. Merck and Co., Inc.

A randomized, multicenter, third party blinded trial comparing oral trovafloxacin vs. IM ceftriaxone for the treatment of nursing home acquired pneumonia. Pfizer, Inc.

Linezolid in the treatment of gram-positive bacteremic infections. An open label, phase II study of intravenous therapy with oral continuation. Upjohn, Inc.

Linezolid in the treatment of *Streptococcus pneumoniae* pneumonia. Upjohn, Inc.

Linezolid vs. nafcillin/dicloxacillin in the treatment of complicated skin and soft tissue infections. A comparator controlled study of intravenous therapy with optional oral continuation. Upjohn, Inc.

Linezolid vs clarithromycin in the treatment of uncomplicated skin and skin structure infections. Upjohn, Inc.

Linezolid for the treatment of methicillin resistant *Staphylococcus aureus* (MRSA) infections. An evaluator blinded trial comparing linezolid with vancomycin alone

and vancomycin followed by oral linezolid. Upjohn, Inc.

Levofloxacin in the treatment of right-sided native valve endocarditis due to *Staphylococcus aureus*. McNeil, Inc.

Departments of Defense and Veterans' Affairs Multi-center Cohort Study evaluating Infection-Associated Clinical Outcomes in Hospitalized Medical Evacuees following Traumatic Injury (TIDOS), Infectious Diseases Clinical Research Program, IDCRP-024

The Acute Respiratory Infection Consortium (ARIC) - A multi-center military consortium for clinical research into the natural history, host response, and potential therapy of acute respiratory infection in military members and their families, Infectious Diseases Clinical Research Program, IDCRP-045.

Severity Symptom Grading Scale for Influenza Infection (FLU-PRO), Infectious Diseases Clinical Research Program, IDCRP-045-01

(principal investigator in the following studies)

A randomized, multicenter, third party blinded trial comparing oral therapy of trovafloxacin vs. oral ciprofloxacin plus clindamycin for the outpatient treatment of diabetic foot infections. Protocol R-0523. Pfizer, Inc.

An open label, non-comparative, multicenter, phase III trial of the efficacy, safety and toleration of voriconazole in the primary and secondary treatment of invasive fungal infections. Protocol 150-604. Pfizer, Inc.

A randomized, comparative, multicenter study of voriconazole versus conventional amphotericin B in the treatment of candidemia in non-neutropenic subjects. Protocol 150-608. Pfizer, Inc.

Randomized, evaluator blind, comparative, phase II study of Ziracin™ (SCH 27899) vs a combination of chloramphenicol and doxycycline in the treatment of vancomycin-resistant enterococcal bacteremia. Study C97-031. Schering-Plough Research Institute.

Open label study of Ziracin™ (SCH 27899) in the treatment of vancomycin-resistant enterococcal (VRE) bacteremia in isolates resistant to chloramphenicol and/or doxycycline. Study C97-269. Schering-Plough Research Institute.

A prospective, multicenter, double-blind, randomized comparative study to evaluate the safety, tolerability, and efficacy of MK-0826 versus piperacillin-tazobactam in the treatment of complicated intra-abdominal infections in

hospitalized adults. Protocol 017-00. Merck and Co., Inc.

LY333328 dose escalation in patients with gram-positive bacteremia. Eli Lilly and Co. Protocol H4Q-MC-ARRC.

A phase II, randomized, multicenter, double-blind, placebo-controlled study to compare two doses of ramoplanin and placebo in the decontamination of the gastrointestinal system colonized by vancomycin-resistant enterococcus. IntraBiotics Pharmaceuticals, Inc. Protocol number 0501.

Invasive fungal infection in liver transplant recipients: a randomized double-blind trial comparing AmBisome® and fluconazole in the high risk group and an observational cohort study in the low risk group. Mycoses Study Group Study #44.

Committee on Energy and Commerce

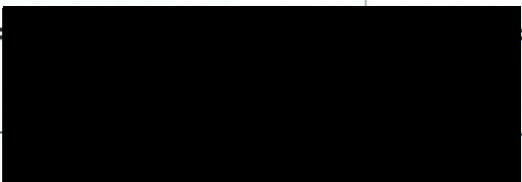
U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"

Required by House Rule XI, Clause 2(g)

1. Your Name: John H Powers MD		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No X
3. Are you testifying on behalf of an entity that is not a government entity?	Yes X	No
4. Other than yourself, please list which entity or entities you are representing: National Physicians Alliance		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that you or the entity you represent have received on or after October 1, 2011: Agency for Health Care Research and Quality Grant 1R18Hs021946-01		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing: Member of NPA FDA Task Force		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	Yes	No X
If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed: Agency for Health Care Research and Quality Grant 1R18Hs021946-01 \$100,000/year for 3 years		
8. Please attach your curriculum vitae to your completed disclosure form.		

Signature: _____



Date: _____

Sept 17, 2014