

Curriculum Vitae

Personal Information:

Alexander Theophil Rakowsky, M.D.

DOB: (b) (6)

U.S. Citizen

(b) (6)

Education:

La Salle University, Philadelphia PA

B.A. Biology/Minor Chemistry

(b) (6)

Hershey Medical College (Pennsylvania State University), Hershey PA

M.D. degree

(b) (6)

Hahnemann University Hospital, Philadelphia PA

Internship and Residency in Pediatrics

(b) (6)

Children's National Medical Center (Washington D.C.) And the Food and Drug Administration (Rockville, MD)

Pediatric Infectious Disease Fellowship

(b) (6)

Work Experience:

Junior Medical Officer/Fellow

Division of Anti-Infective Drug Products (DAIDP)/CDER/FDA

7/93-6/95

Medical Officer

DAIDP/CDER/FDA

7/95-2/99

Medical Team Leader

DAIDP/CDER/FDA

2/99-12/2000

Senior Medical Officer/Pediatric Medical Officer

Office of Biotechnology Activities/Office of the Director/NIH

12/00-6/04

Director of Regulatory Affairs
Research Institute at the Nationwide Childrens Hospital
Columbus, OH
7/04-present

IRB Chair
Nationwide Childrens Hospital
12/04-present

Assistant Professor/Department of Pediatrics
Division of Ambulatory Pediatrics
Attending, Resident Teaching Clinics
Nationwide Childrens Hospital
8/04-present

Awards:

Humanitarian Award, 1988
Awarded to Hershey Medical School student who best “exemplified the ideals of medicine”

Outstanding Pediatric Intern Award, 1991

Outstanding Pediatric Resident Award, 1993

Commendable Service Award/FDA, 1997
For work on drug development aimed at antimicrobial resistant pathogens

Award of Merit/NIH, 2001
For work on an electronic adverse event reporting system for gene transfer studies

Commendable Service Award/Award of Merit/NIH, 2002
For more work on the AE reporting system

Grant Morrow III Teaching Award, June 2007
Presented by Pediatric Housestaff to the Teacher of the Year

Boards/Licenses:

National Medical Boards, three steps (b) (6)

General Pediatric Boards, (b) (6)
Recertified (b) (6)

Ohio Medical and DEA license
Federal DEA license
Inactive: Maryland and Washington D.C. licenses

Publications:

Two chapters on the topic of Rubella in Gorbach, Bartlett and Blacklow's *Infectious Diseases*, second edition

Contributor, 1997 and 2000 editions of the *Red Book, Report of the Committee on Infectious Diseases*, published by the American Academy of Pediatrics

Dowell, Butler...Rakowsky, et al; *Acute Otitis Media: management and surveillance in an era of pneumococcal resistance—a report from the Drug-resistant Streptococcus Pneumoniae Therapeutic Working Group*; Pediatric Infectious Diseases Journal, January 1999, 18(1) 1-9

Heffelfinger, Dowell...Rakowsky, et al; *Management of community-acquired pneumonia in an era of pneumococcal resistance: a report from the Drug-Resistant Streptococcus Pneumoniae Therapeutic Working Group*; Archives of Internal Medicine; May 2000, 160(10), 1399-1408

Singh-Naz, Rakowsky, Cantwell, Patel and Campo; *Nosocomial enterococcal infections in children*; Journal of Infection; March 2000, 40(2), 145-149

Sinus and Allergy Health Partnership (I was one of the authors); *Antimicrobial treatment guidelines for acute bacterial rhinosinusitis*; Otolaryngology-Head and Neck Surgery; July 2000, Volume 123 Number 1, Part 2, supplement

Rakowsky; *The Argument for Excluding Nonimmunized Children From a Pediatric Practice*; Journal of Child Neurology; December 2010, volume 25, 1586-1587

Lectures and Presentations (selected):

FDA/Anti-Infective Drug Products Advisory Committee sessions: presented at 3 focused on antimicrobial resistance issue

FDA/Anti-Viral Drug Products Advisory Committee: presented at the 7-25-00 session

Center for International Development at Harvard University/ “An International Workshop on Antibiotic Resistance: Global Policies and Opinions”, 2-28-00

FDA/DHHS Meeting with the House of Lords (U.K.) Resistance Task Force, 1999

FDA/CDER/ Multiple meetings with Pharmaceutical sponsors regarding their drug development program: spoke at close to 600 and was chair of approximately 200 of these

NIH/NIAID/ Primary Immunodeficiencies and Gene Therapy conference, 2001

NIH/OD/ Presented at three Recombinant DNA Advisory Committee (RAC) meetings

Nationwide (Columbus) Childrens/Grand Rounds, "Regulations and You", February 23, 2006

Resident Lectures (hour long didactics/all residents invited):

"Vaccine Basics": 7/2005, 7/2006, 7/2007, 7/2008 and 6/2010

"Feeding Toddlers": 1/14/09

"Management of Constipation": 5/2/07

"COI and Pharmacy Relationships": 2/1/06 (b) (6)

"Choosing a Research Topic": 1/3/06

Resident Ambulatory Pediatric Block Month Lectures (monthly/45 minutes/8-10 residents per month)

"Evidence supporting what we do in primary care"; 2006-7 academic year

"Quality Improvement": 2007-8, 2009-10 and 2010-2011 academic years

Fellow Lectures (hour long didactic/all fellows invited/presented along with (b) (6))

"COI and Pharmacy Relationships": 1/4/06, 1/13/16; 12/11/07; 3/4/09; 4/7/10 and 12/1/10

Research Institute at Nationwide Children's Lecture Series (Tuesday noon lectures)

"Choosing your research topic": 2005 and 2006

"Responsible Conduct of Research" 2004 and 2005

"Conduct of Clinical Trials" 11/29/05 (along with (b) (6))

"IRB Roundtable": 2006 (Twice, along with (b) (6))

"INDs/IDEs": 8/25/09 and 8/10/10

"Emergency INDs/IDEs": 10/13/09 and 3/30/10

High School Students (Mechanisms of Health class)

Annual presenter each summer from 2006-present

Ambulatory Pediatric Division Lectures

"How to do Research": 9/15/08

"Management of Obesity": 1/30/09

Lounge and Learn lecture series

"How to do Research": 4/11/08

Compliance Education Lecture Series

“Human Subjects Research vs QI”: 12/13/10 and 3/8/11 (along with (b) (6))

Research Conference:

“GCP and IRB issues”: 10/15/10 (Presented along with (b) (6))

Educational Work with Residents:

Categorical Pediatrics Journal Club: co-chair of initiative, 2007-present

Resident Morning Report: Attending coverage (once a month on average), 2005-present

Resident Night Float Report: Attending coverage (twice a month on average) 2009-present

Committees (current):

Nationwide Childrens/ Member of:

Institutional Review Board (chair also), 2004- present

Institutional Biosafety Committee, 2004-present

Safety Committee, 2004-05

Corporate Integrity Committee/Corporate Compliance Committee, 2004-present

Fellowship Scholarship Oversight Committee, 2004-present

Resident Recruitment Committee, 2005-2009 and then 2010-present

Conflict of Interest Committee, 2007-present

Pediatric Resident Journal Club, 2006-present

Central Ohio Pediatric Society, Board, 2008-present

FDA Pediatric Advisory Committee 2008- winter 2012 scheduled to end

External Ad Hoc Reviewer:

Clinical Infectious Diseases, 2001-2008

Outside Memberships:

American Academy of Pediatrics

American College of Pediatrics

Catholic Medical Association

Central Ohio Pediatric Society

Christian Medical and Dental Association