

### PERSONAL INFORMATION Philip Coyne

### WORK EXPERIENCE

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May 2016- Present **Clinical reviewer, Prequalification of Medicines, Dept. of Essential Medicines and Health Products**  
World Health Organization (Switzerland)  
Consultant on team of clinical reviewers who review clinical aspects of submissions to the WHO for prequalification of dossiers for medical products.

June 2014- Present **Adjunct Professor**  
University of Notre Dame, Eck Institute for Global Health (United States)  
Co-director of course entitled 'Global Health Foundations', part of curriculum for Masters of Science in Global Health program. Unpaid position. Since our move to Europe, my role in this program has been reduced to intermittent lectures and meetings with enrolled students.

November 2012-June 2014 **Associate Professor of Tropical Public Health, Department of Preventive Medicine and Biometrics**  
Uniformed Services University of the Health Sciences (United States)  
Course director for Diagnostic Parasitology and Medical Zoology course, comprising 17 lecture hours and 16 laboratory contact hours in the second year medical school curriculum.  
Course director for Medical Parasitology PMO 561, Graduate level 3 credit hour course comprising 20 lecture hours and 20 laboratory contact hours.  
Member, Scientific Advisory Group, Infectious Diseases Clinical Research Program.  
Lecturer for Principles and Practice of Tropical Medicine (PMO 560) and Tropical Medicine Rounds (PMO (both MPH level courses)  
Tropical Medicine consultant to Neglected Tropical Diseases program, Bureau for Global Health, US Agency for International Development.  
US Public Health Service Surgeon Generals representative, Admissions Committee, F. Edward Hebert School of Medicine, Uniformed Services University.

July 2008-November 2012 **Assistant Professor of Tropical Public Health, Department of Preventive Medicine and Biometrics**  
Uniformed Services University of the Health Sciences (United States)  
Same as listed in above listing for Associate Professor entry

November 2003-July 2008 **Program Officer, Antiparasitic Drug Development, Division of Microbiology and Infectious Diseases**  
National Institute of Allergy and Infectious Diseases, NIH (United States)  
Scientific program manager of extramural grants in program M-91 (antiparasitic drug development) comprising 104 grants totaling \$25.6 million dollars in FY07.  
Worked with investigators throughout life cycle of award (R01, R03, R21) as well as with small businesses receiving SBIR (Small Business Innovation Research, R41/42) and STTR (Small Business Technology Transfer, R43/44) grants.  
Branch representative on Clinical Trial Planning Grant committee which determined which R34 and U01 applications would be approved for further processing and possible award.  
Reviewed and approved clinical protocols for studies of antimalarial and antiparasitic drugs in human subjects done under cooperative agreement (U01) awards, along with monitoring and site

visits to clinical trial study sites.

Served as NIAID representative to the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases initiative (DNDi).

May 2001-October 2003 **Associate Director for Regulatory Affairs, Division of Experimental Therapeutics  
Walter Reed Army Institute of Research (United States)**

Detailed from the Office of Global Health Affairs, Office of the Secretary, DHHS

Provided regulatory input to the Director, Division of Experimental Therapeutics, WRAIR, regarding the development of new drugs to prevent and treat malaria, leishmaniasis, and other infectious diseases.

Assisted in the conduct and oversight of antimalarial drug clinical trials in Africa, Southeast Asia, and elsewhere.

Served as Acting Director, Leishmaniasis Diagnostic Laboratory, May-November 2003.

Consulted with DHHS on issues related to Drug Access initiatives, including the Global Fund for AIDS, Tuberculosis, and Malaria.

June 1998-May 2001 **Tropical Medicine Consultant**

The World Bank, Africa Region (United States)

Detailed from the Office of International and Refugee Health, Office of the Secretary, DHHS

Helped conduct the World Bank's efforts in three major tropical disease programs: the Onchocerciasis Control Program and the African Program for Onchocerciasis Control, as well as the Guinea Worm Eradication Program.

Assisted in the development of the Lymphatic Filariasis control program, jointly with the World Health Organization, corporate donors (SmithKline Beecham and Merck), and non-governmental organizations.

Through membership in the Pharmaceuticals Thematic Group and the Interagency Pharmaceuticals Coordination group, assisted in the formulation of Bank policy on pharmaceuticals, and the organization and conduct of educational seminars concerning drug quality and regulation.

July 1991-June 1998 **Medical Review Officer, Division of Anti-Infective Drug Products  
United States Food and Drug Administration (United States)**

Responsible for review of preclinical data and phase 1, 2, and 3 clinical protocols submitted under an IND (Investigational New Drug) application, as well as the NDA (New Drug Application) submission which results from the completed studies. Such review and recommendation serves as the basis for the Agency's regulatory action on that particular NDA, potentially leading to marketing approval of the drug.

Responsible for monitoring adverse drug reaction (ADR) reports on 16 different antiparasitic and antimalarial drugs; initiating epidemiologic consultation when appropriate; and recommending changes in product labeling if indicated.

Accomplishments include completed reviews of five NDAs (including halofantrine, ivermectin, and albendazole), two NDA efficacy supplements (including ciprofloxacin for typhoid fever and cefixime for gonorrhea), and multiple IND applications.

Research included: a clinical pharmacokinetic/pharmacodynamic study to examine the electrocardiographic consequences of co-administration of two antimalarial drugs, mefloquine and halofantrine; and a clinical safety and efficacy study of the causal prophylactic activity of atovaquone in preventing malaria in humans.

## EDUCATION AND TRAINING

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July 1988-June 1991 **Infectious Diseases fellowship**

Walter Reed Army Medical Center, Washington DC (United States)

Three year clinical fellowship in Infectious Diseases including research in the Department of Clinical

Immunology, Walter Reed Army Institute of Research.

July 1985-June 1988

### Internal Medicine residency

Walter Reed Army Medical Center, Washington DC (United States)

Three year clinical residency program in internal medicine at largest US military tertiary care referral hospital.

July 1981-May 1985

### Doctor of Medicine degree

Uniformed Services University of the Health Sciences (United States)

Four year medical curriculum including operational and field medical training unique to the needs of the US military.

## ADDITIONAL INFORMATION

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**Expertise** Neglected Tropical Diseases, Travel Medicine, Global Health

### Publications PUBLICATIONS

1. Drabick JJ, Horning L, Lennox J, Coyne PE, Knight R, Dillard T, Burke D, Fuller S, and Damato J. A retrospective analysis of diseases associated with indeterminate HIV Western Blot patterns. *Milit Med* 156(2): 93-96, 1991.
2. Taylor AJ, Hull RW, Coyne PE, Woosley RL, and Eliasson AH. Pentamidine-induced torsades de pointes: Safe completion of therapy with inhaled pentamidine. *Clin Pharmacol Ther* 49(6): 698-700, 1991.
3. Coyne PE and Maxwell C. Suramin and Therapy of Onchocerciasis (letter). *Arch Dermatol* 128: 698, 1992.
4. Shaver TR, Coyne PE, Peters TG, and Fernandez-Bueno C. Mycoplasma hominis wound infection in a renal allograft recipient. *Res Staff Physician* 39 (1): 72-76, 1993.
5. Eisenhauer MD, Eliasson AH, Taylor AJ, Coyne PE, and Wortham DC. Incidence of cardiac arrhythmias during intravenous pentamidine therapy in HIV-infected patients. *Chest* 105(2): 389-94, 1994.
6. Coyne PE and Addiss DG. Elderly deaths and ivermectin (letter). *Lancet* 350: 215-216, 19 July 1997.
7. Lobel HO, Coyne PE, and Rosenthal PJ. Drug overdoses with antimalarial agents: prescribing and dispensing errors (letter). *Journal of the American Medical Association* 280 (17): 1482, 4 Nov 1998.
8. Aronson NE, Wortmann GW, Johnson SC, Coyne PE, et al. Safety and efficacy of sodium stibogluconate in the treatment of leishmaniasis: recent U.S. military experience. *Clinical Infectious Diseases* 27: 1457-64, 1998.
9. Coyne PE. The Eflornithine Story. *Journal of the American Academy of Dermatology* 45(5): 784-86, 2001.
10. Coyne PE and Berk DW. The Mectizan® (ivermectin) donation program for riverblindness as a paradigm for pharmaceutical industry donation programs. Africa Region, World Bank, May 2002.
11. Shaffer DN, Armstrong G, Higgins K, Coyne PE, Honig P, Boxwell D, Beitz J, Leissa B, and Murphy D. Increased US prescription trends associated with the CDC B. anthracis antimicrobial postexposure prophylaxis campaign. *Pharmacoepidemiol Drug Safety* 12(3): 177-82, April-May 2003.
12. Aronson N, Coleman R, Coyne PE, Rowton E, Hack D, Polhemus M, Wortmann G, Cox K, Weina P, Herwaldt B. Cutaneous Leishmaniasis in U.S. Military Personnel Southwest/Central Asia, 2002-2003. *MMWR* 52 (42): 1009, 24 October 2003.
13. Whitman TJ, Coyne PE, Magill AJ, et al. An outbreak of Plasmodium falciparum malaria in US Marines deployed to Liberia. *American Journal of Tropical Medicine and Hygiene* 83(2): 258-65, 2010.
14. Coyne PE. The World Health Organization Prequalification Programme playing an essential role in assuring quality medical products. *Int Health* 11(2): 79-80, March 2019.
15. Newton PN, Bond KC, Coyne PE, et al. COVID-19 and risks to the supply and quality of tests, drugs, and vaccines. *Lancet Global Health* 2020. Published online April 09, 2020. DOI: [https://doi.org/10.1016/S2214-109X\(20\)30136-4](https://doi.org/10.1016/S2214-109X(20)30136-4)

**Projects** ABSTRACTS listing research projects during my career:

1. Drabick JJ, Horning L, Lennox J, Coyne PE, Knight R, Dillard T, Burke D, Fuller S, and Damato J. A retrospective analysis of diseases associated with indeterminate HIV Western Blot patterns. Montreal, Canada: Fifth International Conference on AIDS. June 1989.
2. Gachihi GS, Were JBO, Coyne PE, Muigai RK, Nyakundi PM, Wasunna KMA, and Sherwood JA. A prospective randomized trial of sodium stibogluconate alone versus sodium stibogluconate plus allopurinol in the treatment of visceral leishmaniasis in Kenya. New Orleans, LA: American Society of Tropical Medicine and Hygiene, 1990 Annual Meeting. Abstract #108.
3. Mason CJ, Coyne PE, Iccayan LO, Sherwood JA, Adoyo MA, Copeland R, Were JBO, Koech DL, Hoffman SL, and Chulay JD. Human lymphocyte proliferative response to polymorphic sporozoite T-cell epitopes correlates with resistance to *Falciparum malaria*. New Orleans, LA: American Society of Tropical Medicine and Hygiene, 1990 Annual Meeting. Abstract #81.
4. Coyne PE, Gerena L, and Milhous WK. Intrinsic antimalarial activity of ciprofloxacin alone or in combination with chloroquine or mefloquine. Boston, MA: American Society of Tropical Medicine and Hygiene, 1991 Annual Meeting. Abstract #233.
5. Mason CJ, Adoyo MA, Klotz FW, Coyne PE, Holland CA, Iccayan LO, Sherwood JA, Copeland RS, Koech DL, Strickland GT, Chulay JD, and Hoffman SL. Human antibody levels to R32LR correlate with lymphocyte proliferative responses to polymorphic *Plasmodium falciparum* CS protein T-cell epitopes. Boston, MA: American Society of Tropical Medicine and Hygiene, 1991 Annual Meeting. Abstract #428.
6. Reed TJ, Coyne PE, and Miller RS. Successful therapy of warm antibody autoimmune hemolytic anemia with intravenous immunoglobulin in a patient with Hodgkin's lymphoma and HIV infection. *Blood* 78 (10) S1: 347a, 1991. Abstract #1380.
7. Coyne PE, Ajayi F, Wiley T, Wortham D, and Cantilena LR. ECG pharmacodynamics and pharmacokinetics of halofantrine and mefloquine. Orlando, FL: American Society for Clinical Pharmacology and Therapeutics, 1996 Annual Meeting, Abstract PII-7.
8. Fleming ER, Mendez J, Tally JD, Figueroa L, Weaver RA, Coyne PE, Aronson NE, and Weina PJ. Analysis of the military clinical workload for the *Leishmania* diagnostic laboratory in the year 2002. Philadelphia, PA: American Society of Tropical Medicine and Hygiene, 2003 Annual Meeting. Abstract #615.
9. Gerena L, Dow GS, Ellis WY, Caridha D, Heady TN, Coyne PE, Magill AJ, Kyle DE, and Milhous WK. Development of stereoselective Lariam analogs would have no advantage over Lariam against emerging resistance in West Africa. Washington DC: American Society of Tropical Medicine and Hygiene, 2005 Annual Meeting. Abstract #818.
10. Coyne PE. Therapeutic options in cutaneous leishmaniasis and a review of the US military experience since 2003. Budapest, Hungary: 11th Congress of the International Society for Travel Medicine, 26 May 2009. Abstract FC03.04.

## Memberships

### BOARD MEMBERSHIP

Board of Directors, Drugs for Neglected Diseases initiative (DNDi), North America 2008 2010  
 Governance Council, Consortium for Parasitic Drug Development  
 2009 2014

President, American Council on Clinical Tropical Medicine and Travelers Health, American Society for Tropical Medicine and Hygiene, 2010 2013

### MEDICAL LICENSURE AND CERTIFICATION

Diplomate, American Board of Internal Medicine, Board Certification in Internal Medicine, September 1988.

Subspecialty Board Certification in Infectious Diseases, American Board of Internal Medicine, November 1992; recertification 2003.

Diplomate, American Society of Tropical Medicine and Hygiene Certification in Tropical Medicine and Travelers Health, December 1997.

Diplomate, International Society of Travel Medicine Certificate in Travel Medicine, May 2005.

Maryland Physician License (active)

Rhode Island Physician License (inactive)

INVITED REVIEWER for

New England Journal of Medicine  
PLoS Medicine  
American Journal of Tropical Medicine and Hygiene  
Emerging Infectious Diseases Journal  
International Journal of Infectious Diseases  
Clinical Infectious Diseases  
Bulletin of the World Health Organization  
Journal of Clinical Microbiology  
Antimicrobial Agents and Chemotherapy  
Malaria Journal  
EDITORIAL EXPERIENCE  
Editorial Board, Military Medicine, June 2010 2014  
Section Editor, Hunters Tropical Medicine (9th Edition) 2011 2012  
COMMITTEE MEMBERSHIP  
Viral Therapeutics Steering Committee, United States Army Medical Research Institute for Infectious Diseases, Ft. Detrick MD, November 2001 October 2003.  
Institutional Biosafety Committee, Walter Reed Army Institute of Research, Silver Spring MD, September 1999 2014  
International Affairs Committee, Infectious Diseases Society of America, October 2002- October 2004.  
Councilor, American Committee for Clinical Tropical Medicine and Travelers Health, American Society of Tropical Medicine and Hygiene, December 2003 December 2006.  
Observer, Expert Scientific Advisory Committee, Medicines for Malaria Venture, Geneva Switzerland January 2004 June 2008.  
Member, Board of Directors, Drugs for Neglected Diseases initiative (DNDi) North America, October 2008 August 2010.  
Data and Safety Monitoring Committees:  
Azithromycin plus Chloroquine for uncomplicated malaria, Pfizer Inc., 2004-06.  
Doxycycline vs Gentamicin for bubonic plague, Centers for Disease Control and Prevention, 2003-07.  
Phase 1/2a trial of genetically attenuated P. falciparum parasites p52/p36 (GAP) vaccine (Chair), Seattle Biomedical Research Institute, April 2010 present.  
Ad hoc reviewer, National Institutes for Child Health and Human Development, Clinical Trials Study Section, October 2006.  
Reviewer, Transformational Medical Technologies Initiative, Defense Threat Reduction Agency, March 2007.  
Reviewer, Military Infectious Diseases Research Program, strategic review of antiparasitic drug research program. American Institute of Biological Sciences, March 2010 present.  
Consultant, U.S. Food and Drug Administration, Anti-infective Drugs Advisory Committee review of NDA 22-268, Coartem® (artemether/lumefantrine). 3 December 2008.  
Consultant, U.S. Food and Drug Administration, Anti-infective Drugs Advisory Committee review of NDA 21-242, artesunate rectal suppositories. 29 April 2010.  
Reviewer, CDC Special Emphasis Panel for FOA CK 11-004, Travelers Health Research: Implementation and Evaluation of Measures to Protect the Health of International Travelers, 10 February 2011.  
Surgeon Generals representative, Admissions Committee, Uniformed Services University of the Health Sciences, September 2011 present.

#### Other Relevant Information