

CURRICULUM VITAE

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EDUCATION & ACADEMIC TRAINING

Purdue University
BSc, Chemistry (1976)
With highest distinction

University of Wisconsin-Madison
PhD, Organic Chemistry (1981)
With highest distinction

Cambridge University, United Kingdom
Postdoctoral Fellow and Research Assistant
Professor (1981-83)

CAREER SUMMARY

(1983 – 1993) SmithKlineBeecham (GlaxoSmithKline) Pharmaceutical Corp. Associate Senior Research Investigator, Senior Research Investigator, Assistant Director

(1993 – 2000) DuPont Pharmaceutical Company Associate Director, Director, Senior Director, Executive Director

(2000 – 2004) Abbott Labs; Pharmaceutical Company Head of Global Chemical Development

(2004 – Present) Howard University Professor of Chemistry and Pharmaceutical Sciences

PERSONAL STATEMENT OF PURPOSE

I am a Professor at Howard University, a Research Tier-1, historically-black college/university (HBCU) in Washington, DC, USA.

I have been a faculty member at Howard University with a joint appointment in the Departments of Chemistry and Pharmaceutical Sciences since 2004. My research group of PhD/PharmD/MSc and undergraduate students creates new science to decrease the cost and increase access to quality-assured medicines in less-developed countries. We have contributed new chemistry and technologies that have improved production and reduced the commercial prices of several drugs for HIV/AIDS. We have discovered new, "green" chemistry to produce the malaria drugs amodiaquine, piperaquine, and lumefantrine. We have also worked on pediatric formulations for the Artemisinin Combination Therapies (ACTs) DHA: piperaquine and artesunate: amodiaquine. We also create new science to lower the dose and improve the safety of essential medicines to promote global access to medicines.

In 2005 I helped found the Drug Access Technical Team (DAT) of the William J. Clinton Health Access Initiative (CHAI). I have had the privilege of contributing to successes in the following areas with CHAI to increase access to medicines for HIV/AIDS, malaria, and TB:

1. The identification of suppliers meeting international standards of quality assurance for generic drug production
2. Negotiating transparent, ceiling prices for Low- and Middle-Income Countries (LMICs)
3. Providing technical assistance to generic suppliers to speed their time-to-market for WHO-Prequalified and US FDA-approved products.
4. Assisting suppliers with achieving regulatory approval for new combinations of drugs (eg, ritonavir/atazanavir; efavirenz/tenofovir/lamivudine)
5. Discovering and transferring novel technology to reduce the cost of Active Pharmaceutical Ingredients (APIs) for HIV/AIDS drugs, including: (a) efavirenz from \$1100 to \$105/kg; (b) tenofovir from \$1100 to \$140/kg; (c) ritonavir from \$3000 to \$450/kg; and (d) lopinavir from \$1900 to \$500/kg.

I presently work with organizations including the World Health Organization, UNITAID, and the Medicines Patent Pool on strategic market dynamics for essential medicines, novel chemistry and regulatory sciences for manufacturing, and regulation of quality-assured medicines for LMICs. I assisted UNIDO (United Nations Industrial Development Organization) and the UN ANDI (African Network for Drugs and Diagnostics Innovation) organizations in implementing the ***Pharmaceutical Manufacturing Plan for Africa***, outlining a strategy that was approved by the Heads of State of the 54 nations of the Organization of African States in June 2012. That strategy has been used to create a National Strategic Plan for Local Pharmaceutical Manufacturing in Ethiopia (2015) in collaboration between the Government of Ethiopia, the WHO and UNIDO. A strategic national plan of action is also being developed for Nigeria (2017). I have been a consultant to the WHO, the Tony Blair Africa Governance Initiative (AGI), and the Governments of Ethiopia and Nigeria in developing these plans.

I regularly teach (2-3 times a year) a curriculum of courses in drug development, GMP and quality-assurance at the University of Ibadan School of Pharmacy (Nigeria) and elsewhere in Africa (e.g., the St. Luke Foundation / Kilimanjaro School of Pharmacy in Moshi, TZ; SLF/KSP). Funding from the German GIZ (Gesellschaft für Internationale Zusammenarbeit) and UNIDO was used to build and equip a drug development facility, classrooms, and a development laboratory at the SLF/KSP. Participants in this training include National Drug Regulators and African pharmaceutical professionals. Attendees learn how to detect counterfeit and substandard drugs, as well as the science and practice of drug development, GMP, quality-assurance and how to write Regulatory submissions. Our objectives are to assist National Drug Regulatory Agencies to achieve Strict Regulatory Authority status and to enable African companies to achieve WHO Prequalification status for their facilities and products. As of 2014 this effort has been expanded into a Master's Degree program at both institutions.

Our work was awarded the American Chemical Society's Astellas Foundation award for "Chemistry Impact on Human Health" in 2009. I was one of four scientists representing the United States at the Chemical Sciences and Society Summit in Beijing, in September 2011. A White Paper from this Conference was provided to agencies of the US Government, including NSF, NIH, and the EPA. I also delivered invited presentations at the WHO ANDI

Stakeholders Meetings in Addis Ababa in October 2011 and January and November 2015. Our African partners have been designated as UN ANDI Centers of Excellence in Drug Manufacturing and Training, and Centers of Excellence in Regulatory Sciences. Our training course in reviewing generic drug submissions received a US FDA “Honor Award” for excellence and innovation in drug training and regulatory sciences. In 2013, I was a recipient of a Team Award from the African Union for Corporate Social Responsibility. In 2015, I was appointed to the Scientific Advisory Board for the Royal Society of Chemistry (UK) “Green Chemistry” division. Most recently, in 2017 I was awarded an honorary membership of the National Association of Industrial Pharmacists by the Nigerian NAIP, and I am also a consultant for the Government of Ethiopia, the WHO and the Tony Blair Africa Governance Initiative on the National Strategy and Plan for Action for Local Pharmaceutical Manufacturing in Ethiopia.

Prior to my faculty appointment, I worked as a scientist and manager in the Innovator Pharmaceutical Industry (from 1983-2004). During that time, I contributed to over 100 New Chemical Entities (NCEs) that moved from Discovery into Development. Thirteen of these new products were approved for commercial marketing, including important drugs for HIV/AIDS, cardiovascular and cancer therapeutics. In my most recent (2001-2004) industrial position I was the Head of Global Chemical Development for a major healthcare company, Abbott Labs, administering annual budgets of up to \$150MM and managing over 400 scientists and technical staff. I am intimately familiar with the science and technology of Active Pharmaceutical Ingredient (API) and finished pharmaceutical product (FPP) drug production. I also have extensive, hands-on knowledge of drug patents, quality assurance, drug regulation, salt selection and physicochemical properties, clinical and marketing (IND and NDA) submissions, and Current Good Manufacturing Practice (cGMP). I was a company representative to the Pharmaceutical Research and Manufacturers Association (PhRMA) Technical Group and contributed to industry collaborations with the US FDA in drafting the ICH Q7A Guidance governing cGMP for the production of APIs.

RECENT AWARDS AND APPOINTMENTS

1. Consultant to the WHO and the Government of Ethiopia in formulating and implementing the National Strategic Plan for Local Pharmaceutical Manufacturing (2016-2017).
2. Consultant to UNAIDS on the Strategic Market Dynamics of implementing Pre-exposure Prophylaxis (PrEP) as part of the long-term plan for eliminating HIV/AIDS (2016-2017).
3. Royal Society of Chemistry's "Green Chemistry" Scientific Advisory Board (May, 2015).
4. Howard University Faculty Senate Award for contributions to Africa and the African Diaspora (May, 2014).
5. Appointment as an Associate Lecturer, University of Ibadan, (May, 2014).
6. African Medicines Regulatory Harmonization (AMRH) designated RCORE Center of Excellence in Regulatory training; St. Luke Foundation / Kilimanjaro School of Pharmacy Industrial Pharmacy Advanced Training (IPAT); Moshi, TZ (April, 2014).
7. WHUR radio interview with our research group on green chemistry and increasing global access to medicines, broadcast on February 13, 2014 available at:
http://wamu.org/programs/metro_connection/13/02/14/this_week_on_metro_connection_chemistry_transcript
8. United Nations Industrial Development Organization (UNIDO) Consultancy on training needs of the South African Pharmaceutical Industry for achieving Strict Regulatory Authority Status (December, 2013).
9. African Union Commission Award for Corporate Social Responsibility (Team), (September 2013).
10. US FDA Honor Award (Team); Kilimanjaro School of Pharmacy IPAT for Excellence and Innovation in regulatory sciences, (September, 2013).
11. "Howard Prof. relies on green chemistry to improve drugs," Interview with National Public Radio reporter Jonathan Wilson broadcast on February 15, 2013. Available on the Internet at WAMU Radio 88.5 "Metro Connection" at:
http://wamu.org/programs/metro_connection/13/02/15/howard_prof_relies_on_green_chemistry_to_improve_drugs
12. Appointed member of the Strategic Advisory Group for funding priorities, UNITAID (2012-2013).
13. Host of the American Chemical Society Webinars on "Green Chemistry" (2012-present; 4-times yearly event).
14. Posted on the American Chemical Society's Nexus Blog: "Dr. Joseph Fortunak: Green Chemistry and Equal Access to Medicines," by Christiana Briddell, December 7, 2012. Accessible at: <https://communities.acs.org/community/science/sustainability/green-chemistry-nexus-blog/blog/2012/12/07/dr-joseph-fortunak-green-chemistry-and-equal-access-to-medicines>
15. United Nations ANDI (African Initiative for New Drugs and Diagnostics) designated Center of Excellence in drug manufacturing and training; St. Luke Foundation / Kilimanjaro School of Pharmacy IPAT (2012).
16. Invited Presenter - American Chemical Society Webinar: "Chemistry, Human Rights, and Health," April 18, 2012. Accessible at:

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