

CURRICULUM VITAE

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EDUCATION & ACADEMIC TRAINING
Purdue University
BSc, Chemistry
With highest distinction
University of Wisconsin-Madison
PhD, Organic Chemistry (1981)
With highest distinction
Cambridge University, United Kingdom
Postdoctoral Fellow/ 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

STATEMENT OF PURPOSE

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

Our research work in COVID-19 has resulted in a (to-date unpublished) new, green synthesis of the drug hydroxychloroquine that reduces the number of chemical steps from 5 to 3 and improves the overall yield. We have also published on the reasonable generic manufacturing costs at commercial scale of drugs for treating COVID-19 (Journal of Virus Eradication, 2020), that has been widely cited in the news media (Le Monde, Reuters, Bloomberg News, San Jose Mercury News, The Guardian; several TV and Radio interviews).

Prior to joining Howard University, I worked for 21 years in the originator pharmaceutical industry as a scientist and manager. I have managed groups as large as 500 people and budgets of \$150MM/year. The drugs that I have brought through development to the market have sold approximately USD\$200Billion.

I joined Howard University in 2004 as an Associate Professor in the Departments of Chemistry and Pharmaceutical Sciences. My research group of PhD/PharmD/MSc and undergraduate students creates new science to decrease the cost and increase global access to medicines of assured quality. We teach drug discovery, development, regulation and quality assurance to African and Asian professionals to promote local pharmaceutical manufacturing in several countries. Our new chemistry and technologies have contributed to greatly reduced prices of several drugs for HIV/AIDS, malaria, and HCV for over 20 million people. We also create new science to lower the dose and improve the safety of essential medicines to promote global access, particularly by discovering novel cocrystals of critical drugs with pharmacokinetic enhancers (PKEs).

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

1. Suppliers meeting international standards of quality for generic production
2. Negotiating transparent, ceiling prices for Low- and Middle-Income Countries (LMICs)
3. Technical assistance to speed time-to-market for WHO-Prequalified and US FDA-approved products.
4. Achieving regulatory approval for new combinations of drugs (eg, ritonavir/atazanavir; efavirenz/tenofovir/lamivudine, dolutegravir/lamivudine/tenofovir disoproxil fumarate).
5. Novel technology to reduce the cost of Active Pharmaceutical Ingredients (APIs) for HIV/AIDS drugs, including: (a) efavirenz from \$1100 to \$95/kg; (b) tenofovir from \$1100 to \$140/kg; (c) ritonavir from \$3000 to \$400/kg; and (d) lopinavir from \$1900 to \$450/kg. Laurus Labs adopted our chemistry for the synthesis of efavirenz to become the lowest-cost supplier of over 2,000 metric tons/year of this API.

I presently work with organizations including the World Health Organization, the TB Alliance, UNITAID, USP, the Bill and Melinda Gates Foundation, and the Medicines Patent Pool on strategic market dynamics, novel chemistry and regulatory sciences for manufacturing, and regulation of medicines for LMICs. Our research team is a Technical Partner with USAID/USP for regulatory systems strengthening and harmonization for the “Journey to Self-Reliance” at part of USAID’s PQM+ Program (\$160MM funding for 5 years).

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.

I regularly teach a curriculum of courses in drug development, GMP and regulatory science 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). Participants include National Drug Regulators, African pharmaceutical professionals, and University faculty. Our objectives are to assist National Drug Regulatory Agencies to achieve Strict Regulatory Authority status and to enable African companies to achieve WHO Prequalification. This effort was expanded into a MSc Degree program in 2014. Since 2008 we have had over 650 people from 21 countries complete our training.

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. 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.

Prior to my faculty appointment, I worked as a scientist and manager in the Innovator Pharmaceutical Industry (1983-2004). I contributed to over 100 New Chemical Entities (NCEs) that moved from Discovery into Development. Fourteen of these new NCEs were approved for marketing, including drugs for HIV/AIDS, cardiovascular disease, cancer, and several autoimmune diseases. In my most recent (2001-2004) industrial position I was the Head of Global Chemical Development I administered annual budgets of \$150MM and managed approximately 500 scientists and technical experts. 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 and polymorph screening and selection and physicochemical properties, clinical and marketing (IND and NDA) submissions, and Current Good Manufacturing Practice (cGMP).

AWARDS AND APPOINTMENTS

1. Technical Collaborator (PI) with the US Pharmacopeia's PQM+ (Promoting the Quality of Medicines) funded by USAID at \$169MM for 2019-2025.
2. Collaborator (PI) with Management Sciences for Health MTaPS (Medicines, Technologies, and Pharmaceutical Services), program to help low- and middle-income countries implement a Global Health Security Agenda with USAID (2018-2013).
3. Consultant to the WHO and the Government of Ethiopia in the National Strategic Plan for Local Pharmaceutical Manufacturing (2016-2018).

4. Consultant to UNAIDS on the Strategic Market Dynamics of implementing Pre-exposure Prophylaxis (PrEP) for eliminating HIV/AIDS (2016-2019).
5. Royal Society of Chemistry's "Green Chemistry" Scientific Advisory Board (May 2015 – May 2019).
6. Howard University Faculty Senate Award for contributions to Africa and the African Diaspora (May 2014).
7. Appointment as an External Faculty member, University of Ibadan, (May 2014).
8. African Medicines Regulatory Harmonization (AMRH) designated Center of Excellence in Regulatory training; St. Luke Foundation / Kilimanjaro School of Pharmacy Industrial Pharmacy Advanced Training (IPAT); Moshi, TZ (April 2014).
9. 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
10. United Nations Industrial Development Organization (UNIDO) Consultancy on training needs of the South African Pharmaceutical Industry (December 2013).
11. African Union Commission Award for Social Responsibility, (September 2013).
12. US FDA Honor Award (Team); Kilimanjaro School of Pharmacy IPAT for Excellence and Innovation in regulatory sciences, (September 2013).
13. "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
14. Appointed member of the Strategic Advisory Group for funding priorities, UNITAID (2012-2013).
15. Host of the American Chemical Society Webinars on "Green Chemistry" (2012-present; 4-times yearly event).
16. 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>
17. 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).
18. Invited Presenter - American Chemical Society Webinar: "Chemistry, Human Rights, and Health," April 18, 2012. Accessible at:
<http://www.acs.org/content/acs/en/global/international/science-and-human-rights/webinars.html.html>
19. Invited Presenter - American Chemical Society Webinar: "Green Chemistry and Global Access to Medicines," presented June 14, 2012
http://article.wn.com/view/2014/07/01/Taxing_the_Sick/

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