Bio

Sam Habet, PharmD., Ph.D., ABCP, FCP, BCPS (pending)
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I was a Senior Clinical Pharmacologist at the US Food and Drug Administration (FDA) in the Office of Clinical Pharmacology (OCP) for 25 years. In addition, I served as Team Leader at the Center for Food Safety and Applied Nutrition (CFSAN) and Policy Lead at the Office of Product Quality (OPQ).

I joined FDA/OCP about 25 years ago and have supported several clinical Divisions and offices at FDA just to name few: Division of Bone, Reproductive and Urology Products, Neurology, Psychiatry, Endocrine, Pulmonary, Analgesia/Anesthesia/Addiction, GI, Oncology, Medical Imaging, CFSAN and OPQ.

As a senior reviewer in clinical pharmacology, I interact with various members of the review team to evaluate the safety and efficacy of drugs. In addition, based on the complexity of the data, I update product labeling to optimize drug therapy in adults, children, and special population such as patients with renal and/or hepatic impairment. In terms of leadership, I have interacted with various team members across the FDA and have developed several presentations related to leadership development with emphases on “soft skills”, “effectiveness”, and “efficiency”.

As part of the review process, I regularly give PowerPoint presentations at least once per week for most of the Investigational New Drugs (INDs) and briefings for all New Drug Administration (NDAs) that I review. From these numerous weekly presentations, I have gained and developed effective communications and presentation skills. My most recent public presentation was on the new oral testosterone product in the US (NDA 206089) presented at the FDA Advisory Committee (AC) on September 18, 2014 (http://www.fda.gov/AdvisoryCommittees/ucm406131.htm). Other two recent AC presentations were for the first in class NME for the treatment of over active bladder (mirabegron, Myrbetric® NDA 202611) and first oral inhaled insulin (Exubera®, NDA 021868), respectively.

I obtained my Ph.D. degree in Clinical Pharmacology from University of London (Guy’s Hospital Medical School, http://www.guysandstthomas.nhs.uk/Home.aspx). I am among approximately 700 scientists worldwide who are certified by the American Board of Clinical Pharmacology (ABCP, http://www.abcp.net). I am also a fellow of the American College of Clinical Pharmacology (FCP, http://www.accp1.org). I am expecting my board certification in pharmacotherapy (BCPS) by Board of Pharmacy Specialties (http://www.bpsweb.org). In addition, I am a registered pharmacist (R.Ph.) in MD, DC, PA, NY, and WA States, certified in CPR, and certified vaccination pharmacist. Therefore, I am regularly practicing pharmacy over 20 years in local hospitals and retail pharmacies such as MedStar and Sinai hospitals.

During my work at the FDA, I have completed several courses and training workshop. For example, I have completed 2 years diploma course in Clinical PharmacoEpidemiology administered by Pennsylvania State University and sponsored by the FDA from 2010 to 2012. In addition, recently I have been nominated by my office to participate in the 2017-2018 course entitled "*American Course of Drug Development and Regulatory Sciences-ACDRS*" sponsored by the FDA and University of California, San Francisco-UCSF (https://pharm.ucsf.edu/acdrs/). I passed the examination and received a **diploma from UCSF** in Drug Development and Regulatory Sciences.

Prior to joining the FDA, I worked in the pharmaceutical industries such as Procter and Gamble pharmaceuticals. As part of my fellowship and training in clinical pharmacology and drug research and development, I worked at the following academic institutions: Florida University, Stanford University, and University of Washington at Seattle. Since 1995, I have been affiliated with New York Medical College in Valhalla, New York as Associate Professor of Pharmacology, a position that I still currently hold. Also, since 1997, I have been affiliated with School of Pharmacy at Howard University as adjunct Associate Professor of clinical pharmacy. From my academic, industrial, and regulatory experience, I have over **40 publications** in peer review journals.

As you can see, I am scientifically well diverse in general health and medical sciences including but not limited to: clinical pharmacology, clinical pharmacy/patient's care, pharmacoEpidemiology, drug regulation, safety, efficacy, and drug development from the academic, industrial, and FDA perspective. I am also diverse in my therapeutic areas within the FDA.