



Chapman Pharmaceutical Consulting, Inc.

Chris Chapman, MD

Veteran USAF 1970 – 1974 Honorable Discharge
Authorized Physician and Surgeon

PO Box 7950
Upper Marlboro, MD 20792
email: cchapman@ChapmanPharmaceuticals.com cell phone: 301-793-3771

EDUCATION

<u>University</u>	<u>Date</u>	<u>Major/Minor/Courses/Degree</u>
Georgetown University School of Medicine	1987	Medical Doctor, MD
Georgetown University School of Medicine	1988	Internal Medicine Internship, Certificate
Georgetown University School of Medicine	1989	Anesthesiology Residency, Certificate
Georgetown University School of Medicine	1991	Cardiovascular, Obstetrics and Critical Care, Anesthesiology Fellowship

EXECUTIVE GLOBAL PHARMACOVIGILANCE EXPERT

Manager of Chapman Pharmaceutical Consulting Inc., a consulting organization that provides support on Product Safety, Pharmacovigilance, Medical Devices, Clinical and Regulatory issues for pharmaceutical and biotech companies in North America, Europe, Japan, India and Africa. Works with Compliance Management Consulting team of former FDA officials in the preparation of FDA Medical Device Guidance including the Medical Device Good Manufacturing Practice (GMP) Regulation. Provides medical device reporting, and post-market requirements. Performed GMP and GLP regulatory device analysis for major laboratories. Completed regulatory GCP and GLP regulatory analysis of adverse events related to Insulin Pumps for Device Company. Expert in Investigator Safety Letters (ILS), Suspected Unexpected Adverse Drug Reaction (SUSAR) Signal Evaluation reports, PADER and PBRER.

- International Pharmacovigilance Software/database expert
 - ARGUS – Oracle Serious Adverse Events
 - Empirica – Oracle Data Mining for Product Safety Signals
 - Trackwise – Patient Compliance and Complaints
 - MedDRA – Medical Dictionary for Regulatory Activities, medical Adverse Event Coding
 - VigiBase – World Health Organization (WHO)
 - FAERS – US FDA Adverse Event Reporting System

CONSULTING WORK

2014 – Present

Astellas Pharmaceutical Inc. (4503:JP) <https://www.astellas.us/therapeutic/product/>

McKesson Corporation (NYSE:MCK) www.mckesson.com

Symphogen Inc. (Denmark) www.symphogen.com

2009 – Present

Takeda Pharmaceutical (NASDAQ: TKPHF) www.takeda.com/products/list-03.html

Akorn Pharmaceutical (NASDAQ: AKRX) https://akorn.com/prod_list_all.php

Church and Dwight Co., Inc. (NYSE: CHD) www.churchdwight.com/brands-and-products/brand-browser.aspx

Sigma Tau Pharmaceutical (Italy) https://sigmatau.com/products/products_prescription.asp

2004

Consultant Manager MiddleBrook Pharmaceuticals product Keflex for Infectious Diseases

Responsible for managing the licensing agreement of Keflex from Eli Lilly to MiddleBrook. Managed worldwide IND Pharmacovigilance, Post Marketing AE's and SAE's that are entered into AERS database and coded in MedDRA.

Manager for staff Enzon Pharmaceuticals

Products Ablecet for invasive fungal infections and Oncaspar for Leukemia. Managed worldwide drug safety and Pharmacovigilance for IND and spontaneous reports. Conducted quarterly epidemiologic, signaling and trending reports. Responsibilities included review of NDA Annual report for labeling changes, pediatric population, and distribution data for quantity and total dosage usage.

Public Board of Directors Appointments

Rock Creek Pharmaceuticals (NASDAQ: RCPI)

Chairman, Chapman Pharmaceutical Health Foundation 501(c)(3)

BioDelivery Sciences International (NASDAQ: BDSI)

Chairman Chapman Pharmaceutical Consulting Inc. S-Corporation

2003 – 2004

Associate Director of Drug Safety, Pharmacovigilance, and Clinical Operations

Organon Pharmaceuticals

Supervised four MDs and ten drug safety specialists. The products included Tice BCG for bladder cancer and Zemuron for Anesthesia. Products for contraception included Nuva Ring, Implanon, Cyclessa, and Desogen. Worked with the German office to review all US and International AE's and SAE reports. Completed review of all Med Watch and CIOMS reports. Sign-off on events in an Organon specific adverse event database. Worked in clinical operations for FDA meetings, IND preparation and medical monitoring of clinical trials. Managed devices for neuromuscular transmission, including 510(k), PMA, IDE, and GMP.

1995 – 2003

Founding Director, Medical Affairs, Drug Safety and Medical Writing Departments

QUINTILES - (Transnational) Durham, North Carolina

Grew Division from no employees to forty employees, including eight board certified physicians, four RNs, two pharmacist, eight medical writers and supporting staff. A Fortune 500 Company.

The Medical Affairs Department supported numerous studies, INDs, device submissions, NDAs and CTAs. Prepared study reports and the ISS and ISE for a drug which was approved by the FDA and EMEA, EurdaCT. Recruited the following Board Certified Physicians in Medical Affairs Department: Internal Medicine, Cardiology, Allergy/Immunology, Neurology, Oncology and Infectious Disease. Responsibilities included Pharmaceutical Development Safety and Pharmacovigilance. Provided advice

and support for preparation of 510(k), IDE, PMA, and PDP. Including cardiovascular and wound devices.

1995 – Present

Attending Physician (Consultant)

Doctor's Community Hospital, Lanham, Maryland

Responsible for the management of quality care for more than 7,000 critically ill patients. Consults with neurologist, internal medicine, cardiologist, surgeons, psychiatrist, G.I., infectious disease, pulmonary, and medical oncologist on the quality of patient care. Manages the resuscitation of over one hundred patients in critical care medicine.

- Medical Intensive Care Unit
- Surgical Intensive Care Unit
- Post Anesthesia Care Unit
- Emergency Room

1992-1994

Medical Director

Regeneron Pharmaceuticals, Inc. Tarrytown, New York (NASDAQ:REGN)

Managed clinical trial safety and efficacy of a Phase I/II study to determine the safety, tolerability, and pharmacokinetics of recombinant human ciliary neurotrophic factor (rHCNRF) in patients with ALS during both acute and subacute administration. Wrote the clinical report and submitted to the FDA. Presented findings of the Phase I/II safety data to the FDA resulting in immediate approval of the Phase III protocol. Designed and implemented quality assurance procedures for monitoring IND clinical trials. Designed and implemented procedures reporting all deaths, hospitalizations, or serious adverse events to IRBs. Visited all 36 sites pre-study, during the study, and post-study. Conducted investigator meetings pre-study and during the study. Responsibilities included licensing, early development and Pharmacovigilance. REGN is one of the top pharmaceutical stocks on Wall Street.

1991 – 1992

Medical Director

Roberts Pharmaceutical Corporation, Eatontown, New Jersey

Managed clinical trials safety and efficacy of Agrelin (Anagrelide), an anticancer drug for the control of excess platelet production in patients with Leukemia. Presented data to the FDA which resulted in an NDA submission and approval. Other products included somagard (a study agent tested for use in the treatment of central precocious puberty, prostate cancer, and endometriosis); maxivent bronchodilator (a study agent tested for the use in the treatment of asthma). Managed all Phase IV studies and post marketing adverse events. Responsibilities included early development of pharmaceutical safety and pharmacovigilance.

Publications on behalf of Loïs Mailou Jones Trust by Dr. Chris Chapman, co-trustee

Loïs Mailou Jones: A Life in Color. biography, published 2007

“New Acquisition: 2004 Louis Vergniaud Pierre-Noel Collection” *Boston Globe*.

“Loïs Mailou Jones” *Art and Antiques magazine*.

“Southern Girl, Loïs Mailou Jones.” *Oxford American: The Southern Magazine of Good Writing*,
January 13, 2010.

Exhibition Review, **Loïs Mailou Jones: A Life in Vibrant Color.** *The Charlotte Observer*, 2010.

Interviews in *Southern Quarterly Magazine, Callaloo*

Websites

www.loismailoujones.com

www.cphf.org

www.at90Iarrived.com

www.chapmanpharmaceutical.com

DRUG PRODUCTS PORTFOLIO UNDER MANAGEMENT

Astellas Pharmaceutical Inc. <https://www.astellas.us/therapeutic/product/>

Adenoscan®, Lexiscan®, ASTAGRAF XL™, Prograf®, AmBisome®, CRESEMBA®, MYCAMINE®, TARCEVA®, XTANDI®, Myrbetriq™, VESicare®

Takeda Pharmaceutical www.takeda.com/products/list-03.html

Pioglitazone Hydrochloride, Alogliptin Benzoate, Candesartan Cilexetil, Azilsartan, Omega-3-Acid Ethyl Esters 90, Trelagliptin, Ramelteon, Galantamine Hydrobromide, Trintellix, Lansoprazole, Dexlansoprazole, Vonoprazan, Vedolizumab, Bortezomib, Leuprorelin Acetate, Panitumumab, Brentuximab, Izazomib

Akorn Pharmaceutical <https://akorn.com/>

Alfentanil HCl Injection
Acetaminophen and Codeine Phosphate Oral
Acetic Acid Otic Solution
Acetylcysteine Injection
Acyclovir Oral Suspension
Adenosine Injection
AK-Fluor® (fluorescein injection)
Akten® (lidocaine hydrochloride ophthalmic)
Amantadine Hydrochloride Oral Solution
Amicar® (aminocaproic acid)
Apraclonidine Ophthalmic Solution
Artificial Tears Ointment (Lubricant Eye Ointment)
Atropine Sulfate Ophthalmic Solution
Azasite® (azithromycin ophthalmic solution)
BAL In Oil™ (dimercaprol injection)
Betaxolol Ophthalmic Solution
Betimol® (timolol ophthalmic solution)
Brimonidine Tartrate Ophthalmic Solution
Bromfenac Ophthalmic Solution
Buprenorphine and Naloxone Sublingual Tablets CIII
Calcipotriene Topical Solution
Calcitriol Injection
Capastat® Sulfate
Chlorhexidine Gluconate Oral Rinse

Ciclopirox Topical Solution, 8% (Nail Lacquer)
Cimetidine Hydrochloride Oral Solution
Ciprofloxacin Ophthalmic Solution
Clindamycin in 5% Dextrose Injection
Clobetasol Propionate Cream
Cogentin® (benztropine mesylate injection)
Cosopt
Cromolyn Sodium Ophthalmic Solution
Cyclopentolate Hydrochloride Ophthalmic Solution
Dehydrated Alcohol Injection
Desoximetasone Gel
Dexmedetomidine Hydrochloride Injection
Dextromethorphan HBr & Guaifenesin Oral Solution
DiaDerm® Foot Rejuvenating Cream
Diclofenac Sodium Ophthalmic Solution
Diltiazem Hydrochloride Injection
Docu Liquid Docusate Sodium
Dorzolamide Hydrochloride - Timolol Maleate
Doxercalciferol Injection
Dronabinol Capsule, USP CIII
Ephedrine Sulfate Injection
Erythromycin Ophthalmic Ointment
Fentanyl Citrate Injection,
Ferrous Sulfate Iron Supplement Drops
Fluticasone Propionate Nasal Spray
Ful-Glo® (fluorescein sodium ophthalmic strips)
Gabapentin Oral Solution

Gatifloxacin Ophthalmic Solution
 Gentak® (gentamicin sulfate ophthalmic ointment)
 Gentamicin Sulfate Ophthalmic Solution
 Gonak (hypromellose ophthalmic demulcent solution)
 Granisetron Hydrochloride Injection
 Guaifatussin AC, Sugar-Free
 Guaifenesin Oral Solution
 HydrALAZINE Hydrochloride Injection
 Hydrocodone Bitartrate and Homatropine Methylbromide
 Hydrocortisone and Acetic Acid Otic Solution
 Hydromorphone Hydrochloride Injection
 Ibuprofen Oral Suspension
 IC-Green® (indocyanine green for injection)
 Ketorolac Tromethamine Ophthalmic Solution
 Ketotifen Fumarate Ophthalmic Solution
 Labetalol Hydrochloride Injection, USP
 Lactulose Solution, USP for Oral Administration
 Lactulose Solution, USP for Oral and Rectal Administration
 Latanoprost Ophthalmic Solution
 Levetiracetam Oral Solution
 Levocarnitine Oral Solution USP
 Levofloxacin Injection, for Intravenous Use
 Lidocaine 2.5% and Prilocaine 2.5% Cream
 Lindane Shampoo, USP
 Loperamide Hydrochloride Oral Solution
 Lorazepam Injection, USP CIV
 LORTAB® ELIXIR CII
 Mag-Ox® 400 Magnesium Dietary Supplement
 Maginex® Advanced Magnesium Supplement
 Methylene Blue Injection, USP
 Midazolam Injection, USP CIV
 Multi-betic® Specifically Formulated for People with Diabetes
 Myorisan™ (isotretinoin capsules, USP)
 Nembutal® Sodium Solution CII (pentobarbital sodium injection)
 Neomycin Sulfate Tablets, USP
 Nystatin Oral Suspension, USP
 Ofloxacin Ophthalmic Solution, USP
 Ophthalmic Solution Eyewash Purified Water, 98.3%
 Orphenadrine Citrate Injection, USP
 Paregoric, USP CIII
 Paremyd® (hydroxyamphetamine hydrobromide)
 Phenylephrine Hydrochloride Ophthalmic Solution
 Physostigmine Salicylate Injection
 PrednisoLONE Oral Solution, USP
 Prednisolone Sodium Phosphate Oral Solution
 Progesterone Capsules
 Promethazine Hydrochloride and Codeine Phosphate Syrup CV
 Protriptyline Hydrochloride Tablets
 Pyrazinamide Tablets
 Pyridoxine Hydrochloride Tablets, USP (Vitamin B-6)
 Ranitidine Syrup (Ranitidine Oral Solution)
 Rifampin Capsules, USP
 Ropivacaine Hydrochloride Injection
 Sufentanil Citrate Injection, USP CII
 Sinus Buster® Nasal Spray
 Sodium Chloride Ophthalmic Ointment
 Sodium Diuril® (chlorothiazide sodium)
 Sulfamethoxazole and Trimethoprim Oral Suspension
 Tetracaine Hydrochloride Injection, USP
 TheraTears® Contact Lens Comfort
 Timolol Maleate Ophthalmic Solution, USP
 Tobramycin Inhalation Solution, USP
 Tranexamic Acid Injection
 Triamcinolone Acetonide Lotion, USP
 Trihexyphenidyl Hydrochloride Oral Solution, USP
 Trimethoprim Sulfate and Polymyxin B Sulfate Ophthalmic
 Tropicamide Ophthalmic Solution, USP
 Uro-Mag® (magnesium oxide)
 Valproic Acid Oral Solution, USP
 Vancomycin Hydrochloride Capsules,
 Vitamin D Supplement Drops
 Xopenex® (levalbuterol HCl) Inhalation Solution
 Zioptan® (tafluprost ophthalmic solution) 0.0015%
 Zostrix® High Potency Arthritis Pain Relief Cream

Church and Dwight Co., Inc. www.churchdwright.com/brands-and-products/brand-browser.aspx
Aim Toothpaste, Answer, Arm & Hammer, Arm & Hammer Spinbrush, Arrid, Auro-Dri, Cameo-
Parkway Records, Carter's Laxative, Close-Up, Delicare, First Response, Gentle Naturals,
Kaboom tile cleaner, Lady's Choice, Mentadent, Nair, Nice'n Fluffy, Orajel, Orange Glo,
OxiClean, Parsons, Pearl Drops, Pepsodent, Pepsodent toothpaste, Rain Drops, Rigident,
RUB A535, Scrub Free, Sedomy Lite, SnoBol, Trojan Condoms, Xtra laundry detergent

Sigma Tau Pharmaceutical (Italy) https://sigmatau.com/products/products_prescription.asp
Cystaran™, Carnitor®, Carnitor®, Matulane®, Adagen®, Abelcet®, DepoCyt®