Dr. David Gortler - FDA Expert

Gortler Biography:

Dr. David Gortler is a pharmacologist, pharmacist and a Yale University-trained pharmacology and molecular biology research scientist. Following his postdoctoral training at the Yale School of Medicine, he worked as an investigational medicine scientist at Pfizer Inc. He later returned to Yale as a didactic/ lecturing professor of pharmacology and biotechnology at the Yale School of Medicine. He was then hired by the FDA and served as a medical officer/senior medical analyst. In his FDA role, he oversaw an multi-disciplinary clinical and scientific support team. He was directly in charge of evaluating the safety and/or efficacy of drugs, FDA labeling changes and whether or not to recommend submitted new drug applications.

He was later appointed to the FDA's Senior Executive Leadership Team where he served as senior advisor to the FDA Commissioner in areas including FDA policy and drug safety. In that role he strongly advocated for FDA reform. He also spearheaded major, critical HHS and FDA initiatives including but not limited to drug safety and the critical examination of the pharmaceutical supply chain, reducing or eliminating animal testing required for drug approval and the quality of drugs from China and India.

Dr. Gortler is an academic authority in the area of pharmacology. He is also an expert in drug development, the process of reviewing and approving new FDA products, FDA regulatory affairs, adverse event reporting/evaluation, the rules and history surrounding FDA approvals or rejections, and a variety of related matters. He has served as an expert and has been invited to testify to congress on several occasions on both general and technically complex matters surrounding FDA regulation, investigational medicine, bioethics, drug safety, FDA shortcomings, and the FDA review/evaluation process.

He is a senior fellow at the Heritage Foundation and a fellow at the Brownstone Institute and www.FormerFDA.com. He has previously served as a fellow at the Ethics and Public Policy Center and has continued to promote meaningful FDA reform.