PROFILE OF DR. GAYATRI RAO

Gayatri R. Rao, M.D., J.D.

Director

Office of Orphan Products Development, Food and Drug Administration

Gayatri R. Rao, is the Director for the Office of Orphan Products Development (OOPD) at FDA. The Office's mission is to advance the development of promising products, including drugs, biologics, devices, and medical foods, for rare diseases. As Director, she oversees a number of key programs created to promote the development of such products on behalf of the agency, including three major designation programs, including the Orphan Drug Designation Program, the Humanitarian Use Device Designation Program, and the Rare Pediatric Disease Designation Program, and two multi-million dollar grant programs, including a $14 million Orphan Products Grants Program, and a $3 million Pediatric Device Consortia Grant Program. In addition, she leads cross-Agency coordination efforts on rare disease issues, including the development of an agency-wide strategic plan on accelerating the development of therapies for pediatric rare diseases, is actively engaged in a number of collaborations both nationally and internationally to promote the development of products for rare diseases, and leads the Office's extensive outreach efforts to patients, sponsors, and other stakeholders.

Dr. Rao received her M.D. from Rutgers, New Jersey Medical School. Upon graduation from medical school, she went on to earn a joint juris doctorate from the University of Pennsylvania Law School, where she concentrated on healthcare and FDA related issues, and a masters in bioethics from the University of Pennsylvania School of Medicine. Following law school, she worked for an international law firm, in Washington, D.C., focusing primarily on food and drug law and other healthcare related matters, including matters related to orphan products. She then joined the FDA's Office of the Chief Counsel where she provided advice on a wide range of issues related to medical devices, combination products, clinical trials, and human subject protection. She brings a unique medical, legal, regulatory, and bioethical background to help move the FDA's rare disease mission forward.