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Regulatory considerations of botanicals as new drugs for the US market

Medicinal use of plant-based products has its origins in antiquity estimated to date back at least 60,000 years. Today approximately 80% of the world's population continues to utilize plants and plant products to treat or prevent clinical conditions. In the United States, plant-based medicines were a major part of pharmaceutical armamentarium that is up until the passage of the US Drug amendments of 1962. The drug amendments further established requirements for new drug approval in the US, specifically requiring that the US Food and Drug Administration must affirm the safety and efficacy of a new drug prior to market approval. It was not until FDA's dissemination of its Botanical Drug Development Guidance document, several decades later, that the US development of botanicals as drugs has experienced resurgence. At present there are two FDA-approved new botanical drugs that are sold exclusively by prescription in the US. This session will discuss how the FDA defines a botanical and the implications of the US regulatory approach on the development and approval of this renewed drug category, along with some of the lingering hurdles to this special category of new drugs.

Biography

Freddie Ann Hoffman, MD founded HeteroGeneity in 2003; a Washington, DC-based consultancy focused on complex natural products, and is also its Managing Member. She has over 35 years of product development experience. She has a BS in chemistry from UCLA and received her MD and General Pediatric Residency training from the University of California at Davis. She completed a fellowship in Pediatric Hematology-Oncology at the National Cancer Institute (NCI), staying on to direct the Nutrition and Supportive Care Section of the Division of Cancer Treatment, and later, as Director of Extramural Clinical Trials of the Biological Response Modifiers Program. Leaving NCI in 1986, she served at FDA for nearly 14 years, as Chief of the Cytokines, Growth Factors and Oncologic Products Branch of the Center for Biologics Evaluation and Research, and later as Deputy Director of the Medicine Staff in the Office of the Commissioner. During her tenure, she formed and chaired an internal FDA Botanical Working Group which developed the botanical drug guidance, which the agency finalized in 2004. She also served in the Office of Dietary Supplements at the Center for Food Safety and Applied Nutrition, before moving to the private sector in 1999, joining Warner-Lambert Pfizer Consumer Healthcare, where she was Senior Medical Director for New Product Development. She continues to serve on numerous working groups, task forces, and boards of both government agencies and private companies. She has chaired and participated in numerous scientific, regulatory and policy forums addressing the development of polymolecular drugs and development of complex product. In 2014, she was an invited speaker at the 18th Presidential Commission on Bioethics (BRAIN initiative). She is a member of the American Society of Pharmacognosy and a past chair of the Drug Information Association's Natural Health Products Track.

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