

Powerful Patient 2009, week 27

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Orphan Drug Development

Joyce talks with Marlene Haffner, retired Admiral in the US Public Health Service. Dr. Haffner served as Director of the Office of Orphan Product Development at the US Food and Drug Administration (FDA) for 20 years. Having worked as a physician provider of medical care, a regulator, and in product development, she has a unique perspective on the development of orphan drugs.



Marlene Haffner, M.D., M.P.H.
Admiral, US PHS, retired

Marlene Haffner was recently honored by Johns Hopkins, from which she earned her Master's in Public Health. Her degree in Public Health is only one of the many dimensions of Marlene Haffner. She is trained in Internal Medicine, Dermatology and Hematology. She is the recipient of numerous professional governmental awards, honors and academic awards.

Marlene has served her country at the highest level of government, rising to the rank of Admiral in the US Public Health Service (USPHS). Dr. Haffner was the director of the Office of Orphan Products Development at the Federal Drug Administration for 20 years, and in that position became one of the world's experts on the research, development, and approval of designated orphan drugs and products for people suffering from rare diseases.

From 1987 to 2004, she was also the FDA Representative to the Office of the Surgeon General, USPHS, holding the rank of Assistant Surgeon General, and focusing primarily on Commissioned Corps policy and initiatives. From 1981 through 1987, she rose from associate director for health affairs at the Bureau of Medical Devices, FDA, to Director for Health Affairs.

Prior to working at the FDA, Marlene was the Area Director of the Navajo Area Indian Health Service in Window Rock, Arizona, administering a comprehensive medical care system which covered an area of approximately 25,000 square miles in the states of Arizona, New Mexico and Utah.

Since retiring from the USPHS in 2007, Marlene served as the executive director, global regulatory affairs and policy for Amgen, Inc. Having worked as a physician, for the FDA, and now for a pharmaceutical company, she has a uniquely broad perspective on the subject of developing therapies for rare disorders.

Her passion remains in making a difference in the health of people so that their lives can be fulfilling and more productive. Her latest enterprise, Haffner Associates, is committed to working with organizations for rare diseases to help them form constructive partnerships with researchers and pharmaceuticals to create and approve drugs for their condition.

Marlene is a Professor in the departments of Medicine, Preventive Medicine and Biometrics at the F. Edward Hébert School of Medicine, Uniformed Services University of Health Sciences (USUHS), and has authored 25 articles in peer-reviewed journals and six book chapters. The Admiral has given almost 300 presentations around the world during her distinguished career.