International Journal of ChemTech Research
CODEN (USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.11 No.02, pp 77-87, 2018

Grants To Stimulate Product Development for Rare Diseases

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Abstract : FDA is committed in advancing rare disease therapies through the development of orphan products. There are about 7000 rare diseases that collectively affect over 30 million people worldwide. The Orphan Drug Act (ODA) of 1983 was signed into law, which is one of the most important parts of health care legislation today. In the past decade before ODA was passed, only 10 treatments were available for rare diseases. The main objective of this study is to compare the situation of rare diseases before and after the developments of the products, and to know the clinical phases (I-IV) involved during the product development process slated for rare diseases. FDA receives funding's from the National Institute of Health (NIH) for the development of products for rare diseases. The growth of pharma industries has slowed in recent years for reasons such as patent expirations, generic competition and stringent regulatory guidelines. Orphan drugs may help pharma companies to reduce the impact of revenue loss caused by patent expires of blockbuster drugs. Although pharmaceutical industry faces many challenges, orphan drugs seem to offer the key for recovery and stability within the market. Rare diseases need more attention due to lack of proper diagnosis and treatment. To treat these rare diseases, USFDA has awarded 18 new research grants totalling more than $19 million to boost development of products for treating rare diseases. The implications of such findings for future development and marketing of therapies for rare diseases are developed.

Key Words : Orphan drug, Grants, Treatment, Funding.

M. P. Venkatesh *et al* /International Journal of ChemTech Research, 2018,11(02): 77-87.

DOI= http://dx.doi.org/10.20902/IJCTR.2018.110210

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