

Dr. Kishor Wasan on a Strategy for Developing Drugs to Treat Neglected Tropical Diseases

Dr. Kishor Wasan discussed a Strategy for Developing Drugs to Treat Neglected Tropical Diseases

SASKATOON, SK, CANADA, November 17, 2021 /EINPresswire.com/ -- Distinguished university scholar and adjunct professor of the Faculty of Medicine at the <u>University of British Columbia Kishor Wasan</u>, who also serves as chief science officer for Skymount Medical US and AmphB Tech Inc., has spent much of his career promoting the development of new drugs to treat relatively uncommon conditions that affect the poorest and most underserved populations of the tropics. He counsels manufacturers that cooperating with the United States Food and Drug Administration



Adjunct professor of the Faculty of Medicine at the University of British Columbia Kishor Wasan

both reduces costs of research and development and expedites delivery of new medications to the people who need them most.

One path to success, <u>Adjunct Professor Kishor Wasan says</u>, begins with the FDA Office of Orphan Products Development (OOPD).

The OOPD work with drugmakers to identify neglected conditions, diseases for which fewer than 200,000 people annually would receive treatment in the United States, as well as treatments for diseases that affect more than 200,000 people annually but that are not expected to earn back research and development costs. The OOPD also identify rare pediatric conditions and conditions of humanitarian concern that may not otherwise meet a pharmaceutical company's criteria for potential market size.

Once neglected conditions have been identified and prioritized, the US FDA provides grant funding for research. Drugs that the US FDA approves for orphan status earn their manufacturers credits against US taxes. administered by the US Internal Revenue Service. They may receive waivers of Prescription Drug User Registration fees, averaging US \$2 million, and

seven years of market exclusivity. During those seven years the US FDA will not approve another regularly approved drug for the same orphan indication.

Designation of orphan drug status is a process separate from approval to market a drug. Medications that have been approved for other indications can be reconsidered for approval as treatments for neglected diseases, resulting in the same incentives to pharmaceutical companies as medications developed de novo.

The chief regulator of the most lucrative pharmaceutical market in the world, the United States, provides strong incentives to meet previously unmet therapeutic needs. Even with these incentives, however, over one billion people are at risk for contracting a neglected tropical disease. Less than 5 percent of research dollars are devoted to finding treatments for 15 percent of the world's people. Using every available resource provided by the US FDA, Adjunct Professor Kishor Wasan believes, is essential for finally developing treatments for neglected tropical diseases.

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