

A New Incentive to Overcome the Market Failure in Public Health Use Pesticides:

Vector Expedited Review Voucher (VERV)

Amend PRIA-4 with a proven new incentive to reduce a significant domestic and global health security risk

Malaria, Dengue fever, Chagas and Lyme disease are vector borne diseases (VBD) carried by insects.

These and several other major global diseases pose a significant biosecurity/health security risk here in the US and abroad.

Major vector-borne diseases account for about 17% of the global burden of communicable diseases. Eighty percent of the world's populations are at risk of one of more vector-borne diseases. Over 700,000 deaths occur annually due to vector borne diseases (VBD).

Pesticides play a critical role in reducing deaths and disease burden. But as shown in malaria, as the use of pesticides increases to reduce mosquito populations so does insect resistance to the products.

We need new, novel insecticides as resistance increases.

The innovation eco-system of private sector, NGO's and government to generate the new pesticides is in a market failure condition. While the population of disease-carrying insects resistant to current treatments has grown, no new class of insecticides have been developed specifically for public health in the last 40 years because there is little profit opportunity to innovate in these markets.

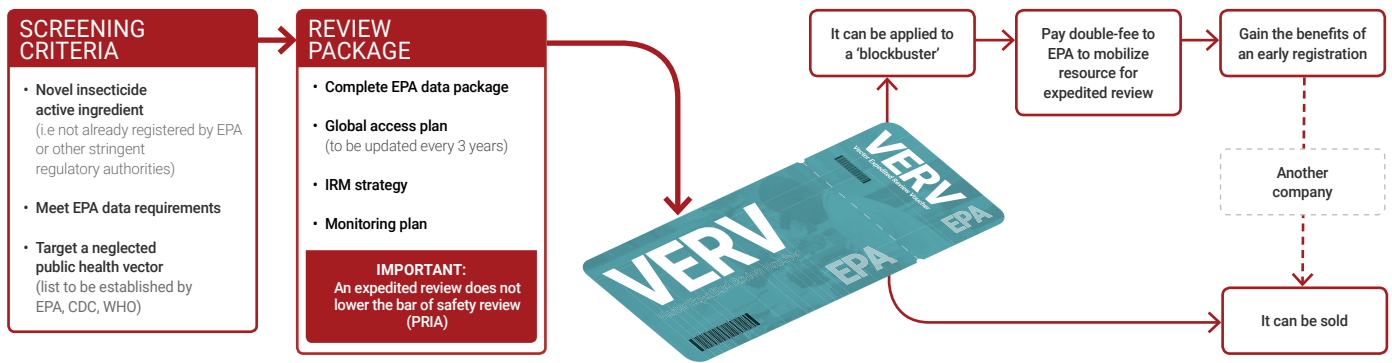
A new incentive is needed to overcome the failure and reduce the global health security risk.

A Vector Expedited Review Voucher (VERV) creates a new incentive for manufacturers who currently do not discover and develop novel new insecticides because the market for VBD insecticides does not provide an adequate return on the development costs.

R&D-based agrochemical companies like Bayer, Syngenta, BASF, Sumitomo and Mitsui need the new incentive to invest in developing insecticide products to control vector-borne diseases like Malaria, Zika, Dengue, West Nile Virus and Chikungunya.

VERV rewards the manufacturer of a new public use insecticide with a voucher to receive expedited review of a second product with no sacrifices in safety or thoroughness. Getting to market faster is valuable and that speed to market acts as an incentive to invest in novel new insecticides for VBD. VERV is modeled after the Priority Review Voucher program (Sec. 524 2007 FDA Amendments Act) that is a proven incentive for neglected tropical diseases (rare pediatric disorders and medical counter measures are also voucher eligible) administered by the FDA since 2008.

How a VERV would work



The FDA has awarded more than 7 priority review vouchers over the past decade (read the history of the PRV program at:

www.priorityreviewvoucher.org).

The program has no cost to taxpayers and the FDA recoups its review costs with a special user fee. PRV's have been exercised by winning companies to bring a new drug more quickly to US patients and vouchers have also been sold to other manufacturers for \$100's millions: the value to manufacturers is a needed incentive to promote discovery and development of much needed treatments for malaria and neglected tropical diseases. The development of a totally novel insecticide from discovery through to launch can cost between \$100-\$250m and take more than twelve years, making a return on investment in vector control markets almost impossible.

The VERV is a virtually no-cost tool to encourage the development of new products to fight infectious diseases on a global scale.

Awarding a VERV gives an innovator company an opportunity to generate a financial return on an agricultural product (most insecticide R&D is done by the ag/crop protection sector) as well as reducing the time to market of critically important public health insecticides to control vector-borne diseases and protect the U.S. from introduced threats such as Zika and West Nile virus.

Novel vector control products can also target Lyme Disease as well as a host of other VBD's prevalent around the world.

Congress is asked to pass an amendment to PRIA 4 that creates a new EPA-administered program: vector expedited review voucher. The program has no cost to US tax payers and review costs borne by EPA would be covered through PRIA dossier review fees to EPA.

In 2017, the researchers published the concept of a VERV in the August issue of the Journal Health Affairs <http://bit.ly/2w7DGZI>

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IVCC is a Product Development Partnership established in 2005 and funded by USAID, PMI, The Bill & Melinda Gates Foundation, UKAID (DFID), the Swiss Agency for Development and Cooperation (SDC), UNITAID, The Global Fund to Fight AIDS, Tuberculosis and Malaria, and the Australian Government (DFAT Indo-Pacific Center for Health Security).

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Duke University's Fuqua School of Business is dedicated to advancing the understanding of management through research and providing the highest quality education for business and not for-profit leaders worldwide.

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