



Vector Expedited Review Voucher (VERV)

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| Agenda

- Historical perspective
- Past as prologue
- Way forward
- Q&A



Vector Control is Critical – “Preaching to the Converted”

- 80% of the world’s population is at risk of insect-borne diseases like malaria, Dengue fever, lymphatic filariasis, leishmaniasis, Chagas disease
- Insect-borne disease impacts health security, poverty rates, labor productivity, education, and gender equality
- The most efficacious and cost-effective approach in tackling these diseases is prevention using vector control tools
- Success of vector control is threatened by insecticide resistance
- Innovative public health insecticides required to address insecticide resistance; achieve goals for disease control e.g. malaria
- Public health use insecticide development is costly, low ROI; product design characteristics for ag insecticides dissimilar to public health use

Priority Review Voucher (PRV) Vector Expedited Review Voucher (VERV)

- PRV & VERV award the registrant of an eligible treatment/insecticide (treatment/vector product) with a voucher to receive an expedited FDA/EPA regulatory review of a second product (voucher product) with no sacrifices in safety
- Faster market entry of the voucher product can generate a financial return to mitigate the investment costs on the treatment/vector product

FDA: pre-existing expedited processes

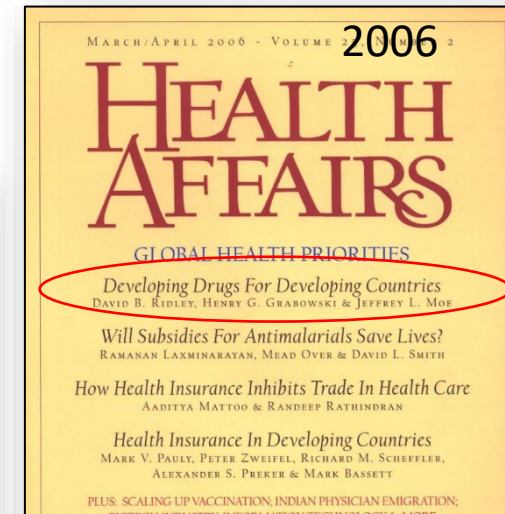
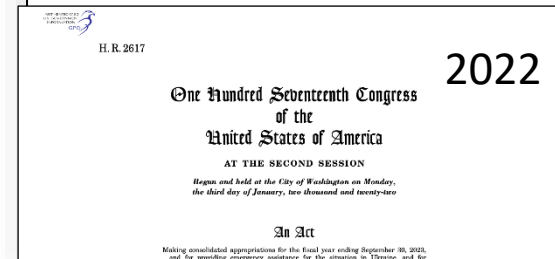
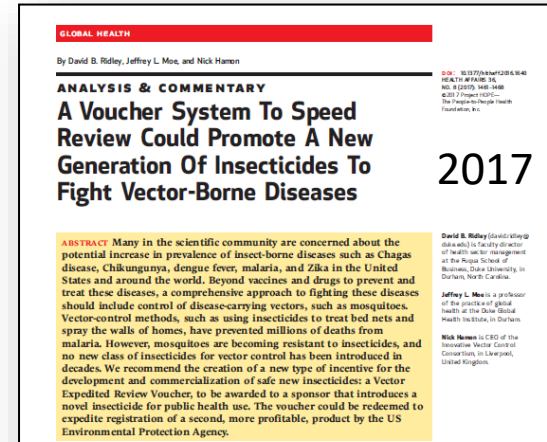
VERV: 5 yrs advocacy to legislation

Gov't & society: low cost

Small incentive: not an advance market commitment

Novelty: not previously approved* (PRV only)

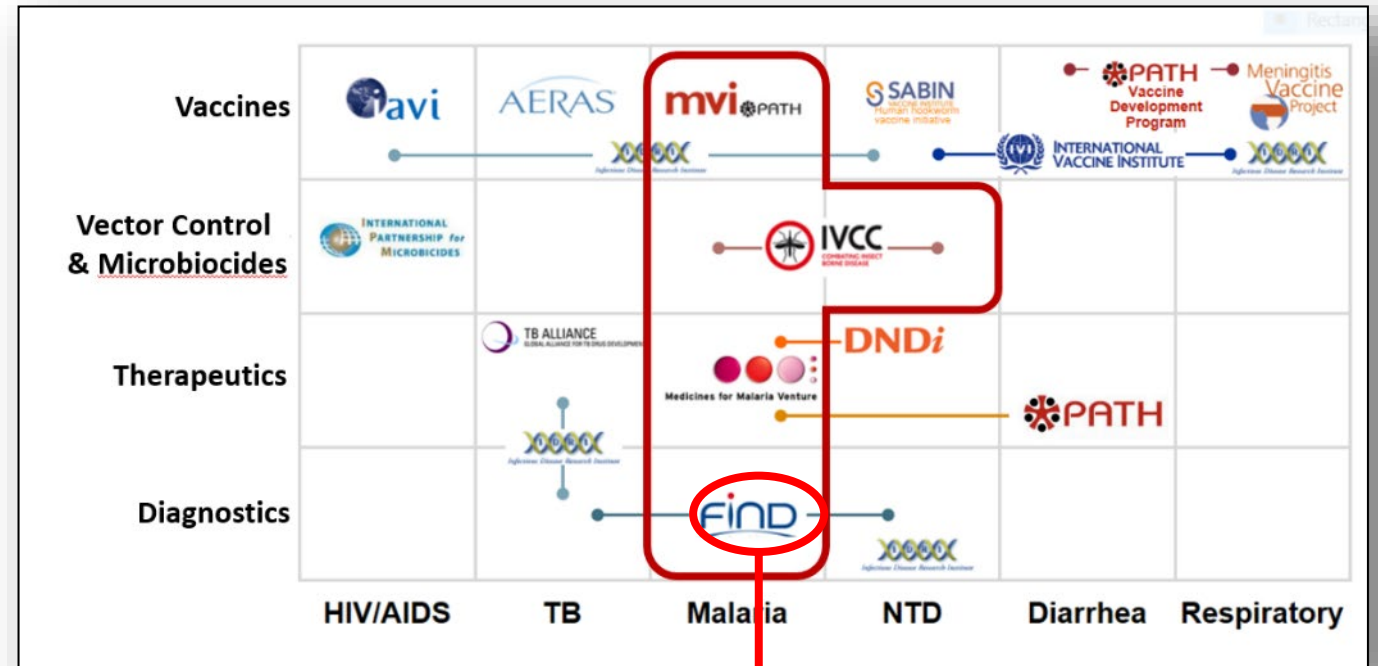
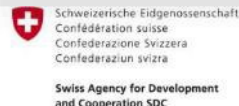
Access: DNA (PRV only)



IVCC Vector Control Product Development Partnership plays unique VERV role

No advocate for PRV - NTD's too broad; potential drug sponsors too diverse for an NGO to coordinate and structure the market

IVCC champions VERV - vector control for malaria lends itself to single organization bringing structure to the market and advocacy



2018-19 research with FIND suggests a Dx voucher incentive infeasible: basis of competition = fast innovation

Market Failure Condition – Policy Targets Unmet Needs

PRV

Low/No
Return on
Investment

Small
unpredictable
markets

VERV

Additional
Regulatory
Hurdles

Resistance

- Blinding trachoma
- Buruli Ulcer
- Chagas
- Cholera
- Chikungunya Virus Disease
- Dengue
- Dracunculiasis
- Fascioliasis
- Filoviruses (Ebola)
- Human African trypanosomiasis
- Lassa Fever (2018)
- Leishmaniasis
- Leprosy

- Lymphatic filariasis
- Malaria
- **Medical countermeasures**
- Meningitis, Cryptococcal
- Neurocysticercosis
- Onchocerciasis
- Rabies
- **Rare pediatric**
- Schistosomiasis
- Soil transmitted helminthiasis
- Tuberculosis
- Yaws
- Zika

- Demonstrates ***proven efficacy against pyrethroid or other insecticide-resistant mosquitoes***
- ***Has a novel or unique mechanism or mode of action***, different from other insecticides already registered by EPA mosquito control
- ***Targets mosquitoes*** capable of ***spreading such diseases*** as *Malaria, Dengue, Zika, Chikungunya, St. Louis encephalitis, Eastern encephalitis, Western encephalitis, West Nile encephalitis, Cache Valley encephalitis, LaCrosse encephalitis, and Yellow Fever*
- ***Is effective in primary malaria vector control intervention areas***, including insecticide-treated nets and indoor residual spray
- ***Meets registration requirements for human health and environmental effects, labeling***, and presents ***no unreasonable adverse effects*** to the environment
- ***Broadens the adoption of integrated pest management strategies***, such as ***insecticide resistance management***, or makes those strategies more effective

Additional Eligibility Requirement – Global Access Plan

- The registrant must submit *a global access plan* that will be *made publicly available* for the *active ingredient* and *product* which includes:
 - *Manufacturing locations*, including any licensed third-party manufacturers
 - *Distribution and procurement processes* for malaria vector control programs in selected countries and the
 - *Prices* for common quantities of the product
- The product must be made *accessible* for use in the *United States*, including *territories* or possessions *of the United States* and *countries* where *mosquito-borne diseases*, such as malaria, *are prevalent*

VERV Additional Eligibility Requirement

The product must NOT:

- Contain in any pesticide product registered by the EPA as of the date of enactment OR
- Contain, as attested to by the registrant, an active ingredient approved in the 2-year period preceding the date of registration by any global stringent regulatory authority for the same uses, vectors, and applications

PUBLIC HEALTH EXCEPTION FOR A PREVIOUSLY REGISTERED PESTICIDE IF THERE IS A SIGNIFICANT PUBLIC HEALTH BENEFIT:

*“If the Administrator determines that there is a significant public health benefit, an active ingredient that is registered for agricultural use that is repurposed and submitted for control of mosquitoes and that otherwise meets the requirements of subclause (I) (excluding items (bb) and (jj)) as determined necessary by the Administrator, **shall be considered a mosquito control product meeting the criteria specified in such subclause**”*

Expedited Review Times on the Voucher Product

| Expedited Review Times | PRIA Category | Active Ingredient Status | Use |
|---|---------------|--------------------------|-------------------------------------|
| 6 months less than the decision review time | R010 | New | Food use |
| 6 months less | R020 | New | Food use; reduced risk |
| 6 months less | R060 | New | Non-food use; outdoor |
| 6 months less | R110 | New | Non-food use; indoor |
| 4 months less | R070 | New | Non-food use; outdoor; reduced risk |
| 2 months less | R120 | New | Non-food use; indoor; reduced risk |



Estimated VERV value

(based on annual sales, by PRIA dossier review category and timeline for conventional pesticides)

| Change in review time | | | Estimated voucher value (\$ millions) based on initial annual sales (\$ millions) of: | | | Changes to estimated value if expedited review > target | | | |
|--|----------------------------|----------------------------------|---|-------|-------|---|-------|-------|-------|
| PRIA* dossier review category | Current PRIA time (months) | Expedited decision time (months) | \$100 | \$200 | \$400 | Actual Review time (mos) | \$100 | \$200 | \$400 |
| New active ingredient, food use | 24 | 18 | \$38 | \$77 | \$153 | 21 (+3) | \$18 | 37 | 73 |
| New active ingredient, food use, reduced risk | 18 | 12 | 39 | 78 | 156 | 15 (+3) | 19 | 37 | 75 |
| New active ingredient, non-food use; outdoor | 21 | 15 | 39 | 77 | 155 | 18 (+3) | 18 | 37 | 74 |
| New active ingredient, non-food use; outdoor, reduced risk | 16 | 12 | 25 | 51 | 102 | 14 (+2) | 12 | 25 | 49 |
| New active ingredient, non-food use; indoor | 20 | 14 | 39 | 78 | 155 | 17 (+3) | 19 | 37 | 74 |
| New active ingredient, non-food use; indoor; reduced risk | 14 | 12 | 12 | 25 | 50 | 13 (+1) | 6 | 12 | 24 |



Building

If target missed by 50%; voucher value reduced ~ 50%

Future requirements and possibilities

PRV past as VERV prologue

- For fiscal years 2023 through 2027, “the focus of the program [VERV] shall be to incentivize the *development of insecticides to **control and prevent the spread of mosquitoes*** bearing diseases...”
- IVCC staff estimates 3-5 novel unregistered products could be eligible ‘23 – ‘27
- Estimating the # of eligible re-purposed products is contingent upon EPA criteria
- Submitted vector product(s) will demonstrate EPA ability to rigorously apply new program criteria
- Sold, awarded voucher(s), if price disclosed, will reveal ONE view of voucher value
- Exercised voucher will demonstrate if/how EPA can expedite review
- 1st PRV awarded to Novartis’s Coartem® 2009; exercised on Ilarus® 2010
- 2nd PRV awarded to Johnson & Johnson’s Sirturo® 2012
- PRV eligibility expanded: NTDs added; rare pediatric disorders, medical counter-measures
 - Voucher value decreased as more vouchers awarded; more anticipated

Next Steps

- Support to EPA
 - Requires some internal IVCC resources
- Communicate VERV opportunity – International Pest Control Journal Articles; Academic Paper (update VERV values; new PRIA categories; other topics)
- Interpret and communicate EPA VERV Guidance to Industry (TBA)
 - Stakeholder Forum in Washington, DC (TBA)
- Continued Unique Role for IVCC
 - Support to EPA – internal and possible external resources in ‘24
 - Advocacy for “Goldilocks” eligibility →←
 - More vouchers = ↓ value; too broad
 - No submissions or awarded vouchers by ‘27 will test stakeholder commitment to PRIA 6 VERV and/or revised eligibility criteria; too narrow

Thank you

Questions