A One-Health Path to Prevent Zoonotic Disease

Presented to the Animal Health Association
October 27, 2015
Challenge: Zoonotic Disease

“The growing risk of zoonotic & vector-borne diseases

“Scientists estimate that more than 6 out of every 10 infectious diseases in humans are spread from animals.”

(CDC 2015)
Solution: One Health
Challenge: U.S. Lyme Disease Epidemic

With an Estimated 300,000 New Cases Each Year, Lyme Disease is the Most Commonly Reported Vector-Borne Infectious Disease in the United States.

Source: CDC
Cost of Lyme Disease in the U.S.

Annual U.S. Cases of Lyme Disease
Centers for Disease Control and Prevention

Direct Medical Costs, Indirect Medical Costs, Lost Income, Lost Taxes, and Related Lyme Disease Costs Per Case as reported in the CDC’s *Emerging Infectious Diseases* and adjusted for 2014 dollars.

Total Annual Cost Burden

\[
\text{300,000} \times \$10,769 = \$3,230,700,000
\]
Solution: Integrated Pest Management

Integrated Pest Management

- Education
- Behavioral
- Landscaping
- Mating Host Control
- Vector Control
- Reservoir Targeted Vaccine
Solution: Reservoir Targeted Vaccine

A disease prevention platform that can address multiple diseases.
RTV Engineering

- Wild pathogen isolated from wild-caught vectors
- Purification of genomic DNA from isolated pathogen
- PCR-cloning of the pathogen antigenic gene
- Antigen gene cDNA cloned into expression plasmid vector
- Antigen plasmid vector transforms E. coli culture
- E. coli culture transformed to express antigenic protein
- Consumed E. coli expressing antigen triggers antibody response in targeted mammalian reservoir
**RTV Technical Considerations**

**Biological Stability**
- Enteric – GALT Delivery
- Inactive – Non-GMO

**Logistics Stability**
- Shelf Life – Multi-month/year
- Temperature – Field Environment

**Production and Cost**
- Flexibility – Multi-species process
- Scalability – Rapid through-put
RTV Production Process

1. Pellets
2. Vaccine
3. Coating
4. Product

LabDiet
LymeShield Production Process & Partners
US BIOLOGIC
HESKA
Agricenter International
Solution: Reservoir Targeted Vaccine

Safe
Effective
Eco-Friendly
Cost Efficient
Because there will always be year-to-year fluctuations in any environmental program, these trend lines are shared to summarize the 5-year, CDC-sponsored RTV field trials published in the *Journal of Infectious Diseases*. Please email steve.zatechka@usbiologic.com to request a full copy of the study and its findings.
Distribution Matched to Tick Cycle

Seasonal activity of *I. scapularis* adults, nymphs, and larvae.

- **Red**: Adult
- **Green**: Nymph
- **Blue**: Larva

**May**

- 18
- 25

**June**

- 1
- 19
- 22
- 29

**July**

- 6
- 27

**August**

- 3
With over 60M people visiting New York parks each year, the state has a keen interest in providing the safest possible environment for its visitors.

“Implementation of such a long-term public health measure could substantially reduce the risk of human exposure of Lyme disease”.

*Journal of Infectious Diseases – Feb, 2014*
Grafton Lakes State Park, Rensselaer County

County Disease Prevalence: 0.38% (611 cases / 159,918 pop.)
Annual Harriman Visitors: 240,063
Lyme Risk: 912 visitors / year (0.38% x 240,063)
Total Acres: 2,500
Estimated Y1 Protected Acres: 625 acres (25% total acreage)
Cost of Protection / Visitor: $0.26 / visitor

Note: Numbers do not include the CDC’s 10X under-reporting factor.
One Health Regulatory

• ORV and now RTV both are under USDA guidance

• Continue to partner with EPA, FDA, and USDA to build a cohesive pathway for rapid development and deployment.
Oral-Delivery Solution Pipeline

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<th>Product</th>
<th>Discovery</th>
<th>In vitro</th>
<th>In vivo</th>
<th>Licensure Process</th>
<th>Market</th>
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US BIOLOGIC Technology Recognition

Winner of $1 Million Global Food & Health Innovation Challenge

Top Memphis Innovation

National Media Recognition
US BIOLOGIC Leadership Team

Mason Kauffman
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Retired Chief, USAMRIID
Boston, MA, Resident

Dave Williams
Board Member
Retired Chairman &
CEO of SANOFI

Gov. Tommy Thompson
Board Member
WI Governor for 14 years
U.S. Secretary of Health
& Human Services

MG Bill Suter
Political Advisor
Retired Clerk of US
Supreme Court

Maria Gomes-Solecki, DVM
Inventor, Science Advisor
Thank You

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