

# Incentivizing the Development of Vaccines to Combat Antibiotic Resistance

## Recommendations from the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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- Antimicrobial Resistance Working Group
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Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

# Disclosure Statement

Timothy Cooke is Chief Executive Officer, Board Director and shareholder in NovaDigm Therapeutics, a company engaged in the development of vaccines against antimicrobial resistant pathogens including *Candida* and *Staphylococcus aureus*.

# Overarching Task

PACCARB's task was addressing the best way to incentivize the development of therapeutics/anti-infectives (including alternatives to antibiotics), rapid diagnostics, and vaccines for both humans and animals.

# Approach

Created 3 Working Groups:

- Incentives for Vaccines Working Group
- Incentives for Diagnostics Working Group
- Incentives for Therapeutics/Anti-Infectives Working Group

# Approach

Working Groups developed an analysis framework based on issues and recommendations divided into four broad themes:

- **Economic-** Issues that influence the ROI to companies or food animal producers regarding product development or use
- **R&D-** Issues related to discovery research and the development process
- **Regulatory-** Issues related to the federal regulatory processes that influence the development or modification of a product ranging from basic research through studies that meet approval criteria
- **Behavioral-** Issues related to the behavior of consumers, providers, and companies relative to product use or development

## Human Health

## Incentives to Develop

## Animal Health



Provide additional funding for the development of new product pipelines for vaccines that prevent viral or bacterial syndromes that drive antibiotic use



Optimize the Interactions among sponsors, regulatory agencies (such as FDA), and use policy committees (e.g., the ACIP)



Incentivize the uptake of vaccines by influencing behavior, such as reimbursement to ensure "first-dollar coverage"



### Vaccines

Develop and fund a National Policy and Innovation Institute under USDA whose main functions will include the following:



Support basic research on immunology across species for the development of vaccines



Include the development of a concomitant rapid AST as part of any new antibiotic funding (or funding for new antibiotics)



Provide financial support for diagnostic manufacturers to bring new tests to market



Continue funding for clinical trials networks with common rules or shared IRBs



### Diagnostics



Promote educational programs for veterinarians on the use and interpretation of diagnostic tests



Develop new economic models (pull incentives) for therapies to support the currently available push incentives



### Therapeutics / Anti-Infectives



Provide resources to conduct, evaluate, and create a database of efficacy studies of alternative products

## Human Health – Vaccines

- Provide additional funding for the development of new product pipelines for vaccines that prevent viral or bacterial syndromes that drive antibiotic use
- Optimize the interactions among sponsors, regulatory agencies (such as FDA), and use policy committees (e.g., the ACIP)
- Incentivize the uptake of vaccines by influencing behavior, such as reimbursement to ensure “first-dollar coverage”



# Economic Recommendations

Issue Statement	Recommendation
<p>Federal and nonfederal stakeholders lack a common understanding about the current and potential economic value and societal impact of vaccines that can reduce AMR.</p>	<p>Analyses on the cost and societal impacts associated with new vaccine development and administration in the AMR arena developed via a multi-agency process that involves at least CDC, CMS, and Treasury, in partnership with industry and public health stakeholders.</p>
<p>There is limited funding for developing infectious disease vaccines, in particular for those targeting AMR-related pathogens.</p>	<p>An expanded range of incentives to encourage development of vaccines that could reduce AMR by preventing the syndromes caused by bacteria and viruses that lead to antibiotic use.</p>



# R&D Recommendations

Issue Statement	Recommendation
<p>There are insufficient epidemiological data on antibiotic use for infections caused by pathogens currently or potentially preventable through vaccination.</p>	<p>Expanded surveillance by the CDC and CMS to measure antibiotic use due to infections that could be prevented or reduced by vaccination to assess the impact or potential impact of prevention through immunization, either by existing or to-be-developed vaccines.</p>
<p>The clinical-stage pipeline for vaccines targeted specifically against bacterial pathogens associated with AMR is weak.</p>	<p>Focused financial incentives to encourage the development of vaccines directed at pathogens that have high rates of AMR across the R&amp;D continuum (from early to advanced development).</p>



# Regulatory Recommendations

Issue Statement	Recommendation
<p>The lack of clarity about regulatory pathways for vaccines focused on AMR reduces the willingness of sponsors to produce vaccines.</p>	<p>Early interaction between sponsors and FDA and workshops, hosted by FDA's Center for Biologics Evaluation and Research (CBER), explaining pathways and best practices.</p>
<p>The potential market for a new vaccine (as opposed to other AMR products) is uncertain, because vaccine uptake is heavily influenced by recommendations of the Advisory Committee on Immunization Practices (ACIP) and funding for vaccination.</p>	<p>Early communication between the manufacturer, FDA, and CDC to present and discuss a target product profile with particular reference to impact on AMR pathogens.</p>



# Behavioral Recommendations

Issue Statement	Recommendation
<p>Implementation strategies for optimal vaccine acceptance and utilization are inadequate.</p>	<ol style="list-style-type: none"> <li>1. Programs and interventions based on behavioral insights that aim to increase vaccine uptake.</li> <li>2. Continued, broadened economic incentives to influence behavior and increase uptake, such as reimbursement to ensure “first-dollar coverage”—that is, insurance coverage of vaccines without copayments or coinsurance costs for all ages, not just children.</li> </ol>
<p>Providers lack knowledge about the role of vaccines in preventing AMR.</p>	<p>Focused governmental vaccine-centric educational policies and approaches, including vaccination as a means of achieving antibiotic stewardship, with involvement of health care facilities and health-related educational institutions (e.g., medical schools, academic health centers).</p>

# Acknowledgements

Thank you to all Incentives for Vaccines Working Group members:

Co-chairs: Kent Kester (human health) & Randall Singer (animal health)

Members: Helen Boucher, Aileen Marty, Robert Weinstein, Jay Butler, Elizabeth Wagstrom, Joseph Larson, Cyril Gay, Peter Marks, Jane Knisely, Barbara Mulach, Anthony Fiore, Brian McCluskey, Kim Thompson\*, Tim Cooke\*, David Fleming\*, Ann Ginsberg\*, Saad Omer\*, Nate Smith\*

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