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# Animal Health

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# Introduction

- Veterinary medicine is more diverse than human medicine
  - Animal species, living environments, diseases, business structures, etc.
  - For food animal medicine, veterinarians and producers use a population health management approach to ensure animal health and welfare is balanced with public health and food safety considerations: disease prevention, early detection and diagnosis of disease outbreaks, appropriate treatment and review outcome
  - Therapeutic antibiotic products are still needed to treat disease outbreaks yet there are few, if any, new candidates in development, so stewardship is vital
- Continuing trend toward minimizing antibiotic use in food animal production
  - Veterinarian oversight, consumer food preferences, food company programs (e.g. Raised Without Antibiotics), regulation, etc.

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## **Introduction cont.**

- To continue to reduce the use of medically important antibiotics in animal agriculture, additional vaccines and non-antibiotic alternatives that contribute to disease intervention are needed, along with improved diagnostic tools
- Proposal for Innovation Institute within USDA to facilitate R&D on these three areas with an accompanying National Policy on Alternatives to Antibiotics in Food Animals to guide the effort
  - Entrepreneurial coordinating and resource center for start-ups, universities, researchers, and small companies
  - Intended to complement and streamline ongoing activities within USDA, FDA CVM, and other agencies, plus establish connectivity with various animal health organizations, funders, companies, etc.

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# Incentives for Vaccines

WG Co-chair: Randall Singer

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# Overview

- Idea of how to incentivize new vaccine development and use is novel concept for agriculture
- Two ways in which vaccine use could reduce emergence and spread of AMR bacteria:
  - Vaccines prevent diseases in animals so that fewer antibiotics are needed for treatment
  - Vaccines could target zoonotic bacteria carried by healthy animals but potentially pathogenic to humans
- Cost of vaccines and administration is completely borne by farmers

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# Economic

**Issue 1:** The cost of purchasing and administering vaccines can outweigh the cost of purchasing and administering antibiotics. (27)

- **WG Recommendation:** Incentives for the use of vaccines that reduce bacterial disease prevalence in farm animals to reduce the need for antibiotics

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## **R&D**

**Issue 1:** There is limited funding for basic research on the immune system in key animal species, which is fundamental to designing the next generation of vaccines, adjuvants, and administration tools. (28)

- **WG Recommendations:**

1. New funding dedicated to supporting basic research of immune systems across food animal species to optimize vaccine development, with shared funds across agencies, as this issue addresses AMR in both human and animals
2. Sufficient funding for the proposed Innovation Institute within USDA to develop new technology accelerator programs

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## **R&D cont.**

**Issue 2:** Vaccine delivery systems for mass vaccination are not optimized for specific animal-pathogen-production scenarios. (29)

- **WG Recommendations:**

1. New funding dedicated to supporting improved vaccine delivery in animal production, with shared funds across agencies, as this issue addresses AMR in both human and animals
2. Sufficient funding for the proposed Innovation Institute

**Issue 3:** Epidemiological data are insufficient about the use of antibiotics for infections caused by pathogens that are currently or potentially preventable through vaccination. (30)

- **WG Recommendation:** Increased collaborations with public-private partnerships and specific studies to estimate amount of antibiotic use that can be eliminated with vaccines, including viral disease vaccines

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# Regulatory

**Issue 1:** Regulatory processes prevent a flexible approach and rapid approval of vaccine strain updates in vaccine development. (31)

- **WG Recommendation:** Process evaluation by USDA's Center for Veterinary Biologics (CVB) to improve speed of approval of new strains in commercial vaccines

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# Behavioral

**Issue 1:** It is challenging for producers and veterinarians to integrate new vaccines and vaccination strategies into overall health management strategies while balancing productivity and welfare with ROI. (32)

- **WG Recommendation:** Education and training in assessing the effectiveness of disease prevention programs that balance productivity and welfare through improvements in veterinary and animal science curricula, continuing education, and funding for training programs that assess herd and flock health programs

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# Incentives for Diagnostics

WG Co-chair: Peter Davies

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# Overview

- Advanced animal diagnostic infrastructure of US veterinary laboratories
- Ability to rapidly develop, implement, and scale up diagnostic testing to meet industry needs
- Companion animal diagnostics

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## **Economic**

**Issue 1:** Clinical outcome studies are needed to show that the use of diagnostic tests could prevent or quickly detect the emergence of antibiotic-resistant bacteria and is cost-effective. (33)

- **WG Recommendation:** Increase funding of diagnostic outcomes studies, including animal health and welfare outcomes, AMR, and the impact on cost of production

**Issue 2:** The use of diagnostic testing can be limited by the expense incurred. (34)

- **WG Recommendation:** Ongoing financial support for veterinary diagnostic laboratories that perform diagnostic testing and AST for animal pathogens

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# R&D

**Issue 1:** Few tests rapidly identify pathogens or provide rapid susceptibility results in food animal medicine. (35)

- **WG Recommendations:**

1. Investment in research on diagnostics that rapidly identify pathogens in food animals or provide rapid susceptibility results directly from the clinical specimen in the field setting
2. Investment in translational research to adapt diagnostics platforms developed for humans to animals

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## **R&D cont.**

**Issue 2:** Novel diagnostics are needed to advance process control in the harvest and postharvest sectors of the food supply chain to reduce exposure risk. (36)

- **WG Recommendation:** Support for research to develop culture independent methods for detecting microbial contamination of carcasses and meats to support improved process controls.

**Issue 3:** Additional information is needed on AST for key animal pathogens, including validated clinical breakpoints. (37)

- **WG Recommendation:** Research grants for the generation and integration of additional data necessary for the Clinical Laboratory & Standards Institute (CLSI) to establish test methods, quality-control range data, and interpretive categories (i.e., breakpoints) for priority animal pathogens for which there are currently none available or where human breakpoints are used

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# Regulatory

There is no regulatory issue identified

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# Behavioral

**Issue 1:** There is negligible evidence-based data about how veterinarians incorporate diagnostic testing in making decisions to employ antibiotic therapy. (38)

- **WG Recommendations:**

1. Support for research into therapeutic decision-making behavior in veterinary medicine, including the use of AST and the potential for rapid diagnostics
2. Educational programs for veterinarians on the use and interpretation of diagnostic tests and stronger curricula and continuing education programs linked to antibiotic stewardship

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# Incentives for Alternatives

WG Co-chair: Tom Shryock

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# Overview

- Definition of alternatives- nonantibiotic disease interventions administered to food animals and can include categories such as microbial-derived products, phytochemicals, immune-modulating products, and nutritional supplements
- Multiple external pressures, such as consumer preference and restriction on the use of medically important antibiotics, have diminished the market for antibiotics in food animals

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# Economic

**Issue 1:** Funding is lacking to generate a sufficient pool of quality alternative candidates at the early and middle stages of R&D. (39)

- **WG Recommendation:** Sufficient funding for the proposed Innovation Institute within USDA to develop new technology accelerator programs

**Issue 2:** Many alternatives on the market do not have efficacy data comparable to that of antibiotic products, yet they are preferred by food animal producers over more expensive antibiotics or alternatives that have proven effectiveness via a regulatory approval process. (40)

- **WG Recommendation:** Enhanced support for small business innovation on alternatives through existing government programs (e.g., SBIR funding) and private-sector investment incentives

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## R&D

**Issue 1:** Small companies and independent innovators do not have readily available resources to conduct key studies that de-risk alternatives. (41)

- **WG Recommendation:** Sufficient funding for the proposed Innovation Institute to provide support services and serve as a clearinghouse to connect innovators to the needed resources for R&D and appropriate use of innovative, nonantibiotic alternatives for animal disease intervention

**Issue 2:** Due to insufficient comparative data for alternatives and antibiotics, there is an incomplete understanding on how best to use an alternative product(s) in food animal production settings and how a new product can provide an added benefit compared to the existing ones. (42)

- **WG Recommendation:** On-farm demonstration trial research project grants to researchers or food animal production companies to fund and conduct field studies using an alternative product(s)

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# Regulatory

**Issue 1:** Early-stage developers of alternatives face the challenge of determining which regulatory agency has jurisdiction over their candidate. (43)

- **WG Recommendation:** Support for the proposed Innovation Institute to act as a single point of contact for basic research scientists and small companies to obtain feedback from the Center for Veterinary Medicine (CVM) and USDA

**Issue 2:** There is no standardized regulatory guidance for developers of alternatives because of the diversity of types of alternative products. (44)

- **WG Recommendation:** Ongoing exploration of novel technologies to inform FDA CVM and USDA efforts to find new ways of satisfying evidentiary requirements via innovative regulatory approaches appropriate for the alternative candidates

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# Behavioral

**Issue 1:** Researchers lack awareness of the business value and process of patenting novel technology which may result in public disclosure, thereby diminishing value of the technology. (45)

- **WG Recommendation:** Awareness of the need and process for initiating patent protection of new technologies, included as part of the educational resources and outreach efforts of the proposed Innovation Institute

**Issue 2:** Stakeholders have not fully accepted alternatives to antibiotics because they lack trust in their effectiveness and safety. (46)

- **WG Recommendation:** Analysis of information gathered in a database repository from alternative product demonstrations to assess how innovative technology may or may not have minimized the identified consequences while maximizing the health outcomes and possibly affected business aspects (e.g., ROI)

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# Conclusion

Thank you to all WG members:

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# Council Discussion

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