March 31, 2010

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases (proposed)
Office of Antimicrobial Resistance
1600 Clifton Road, NE., Mailstop A–07
Atlanta, Georgia 30333


Dear Sir or Madam:

The American Veterinary Medical Association (AVMA), established in 1863, is a not-for-profit association representing more than 80,000 veterinarians working in private and corporate practice, government, industry, academia, and uniformed services. Structured to work for its members, the AVMA acts as a collective voice for its membership and for the profession.

The Public Health Action Plan to Combat Antimicrobial Resistance, (Action Plan) developed by an Interagency Task Force on Antimicrobial Resistance in 1999, reflected a broad-based consensus of federal agencies and other stakeholders on actions needed to address antimicrobial resistance (AR). At the time there was wide recognition that complete implementation of the plan would require close collaboration among state and local health agencies, universities, professional societies, pharmaceutical companies, health care delivery organizations, agricultural producers, consumer groups, and other members of the public. The plan was expected to be implemented incrementally, dependent on the availability of resources.

The AVMA was a key stakeholder in the development of the Action Plan, helping to ensure that the plan provided a blueprint detailing coordinated federal actions that are critically needed if we are to mitigate the threat of antimicrobial resistance: Surveillance, Prevention and Control, Research, and Product Development. Since the development of the Action Plan, the AVMA has consistently been supportive of the plan and advocated for funding to fully implement the plan.

The AVMA applauds the Interagency Task Force and its collaborators for advancements made in combating antimicrobial resistance. We assert, however, that upon publication of annual progress reports, inclusion of status updates regarding completed, current, and new projects would allow a more comprehensive view of the successes gained and barriers encountered in implementing the Action Plan. For example, we recognize that some projects such as the National Antimicrobial Resistance Monitoring System (NARMS) were developed as a result of the Action Plan and have had periodic programmatic changes, which could be included as status updates within the published Action Plan. Other projects may not be as widely recognized, but are certainly noteworthy and still warrant progress reports.
While we appreciate the efforts of the Interagency Task Force to embark upon the complex issue of antimicrobial resistance, I am writing to you today to share three main concerns the AVMA has regarding implementation of the Action Plan:

- We contend that this Action Plan represents precisely what is needed to tackle the threat of antimicrobial resistance, yet the animal and veterinary components of the plan have been continually underfunded.
- Of the original 13 Top Priority Action Items (identified in **bold** below), few actions have targeted animal health or yielded results that can mitigate antimicrobial resistance in animals, and therefore transmission to humans.
- Other Action Items that target animal health still require additional funds and efforts for full implementation.

**Action Items currently lacking animal health projects:**

**Surveillance**

*Action Item 5 – Develop and implement procedures for monitoring patterns of antimicrobial drug use in human medicine, agriculture, veterinary medicine, and consumer products*

- The AVMA believes that much of the debate on the use of antimicrobials in animal agriculture is a result of data gaps, including patterns of antimicrobial use.

*Action Item 6 – Identify and evaluate methods for collecting (e.g. optimal sampling methods) and disseminating the surveillance data on antimicrobial usage.*

- In veterinary medicine, there is a lack of optimal sampling methods for collecting surveillance data on antimicrobial usage. In fact, little data if any data are available that provide any detail regarding specific uses.

*Action Item 13 – With state health and agriculture departments and other stakeholders, define needed core capacity (the minimum needed in human, laboratory, and electronic resources) at the state and local level to ensure that basic AR surveillance is conducted in these jurisdictions.*

*Action Item 14 – Provide resources to assist in meeting state and local core capacity needs for AR surveillance.*

*Action Item 15 – Provide an accessible, centralized source of AR data from major surveillance systems involving animal and human populations*

- Projects appear to focus on human populations and are somewhat decentralized. No projects were identified that permit analysis and comparison of trends regarding drug use and medical and agricultural practices.

**Prevention and Control**

*Action Item 46 – Educate the public about the merits and safety of irradiation as one tool to reduce bacterial contamination of food.*

*Action Item 54 – Identify and evaluate new food pasteurization strategies*

*Action Item 56 – Assess the impact of antimicrobial use in companion animals (pets) on colonization and infection with drug resistant organisms in the animals and their human household contacts*
Action Item 57 – Work with veterinary and agricultural communities to help educate users of veterinary and agricultural antimicrobials about AR issues, and promote the implementation and evaluation of guidelines that address these issues.

- The AVMA’s Judicious Therapeutic Use of Antimicrobials Guidelines was developed to address these issues. We desire continued collaboration with the agencies and species specific organizations that helped us develop these guidelines to continue refining and the guidelines as needed.

Action Item 60 – Evaluate the potential impact of making all systemic veterinary antimicrobial drugs available by prescription only.

- The AVMA strongly urges that evaluation of both risks and benefits to humans and animals be considered prior to any mandatory action.

Action Item 61 – Convene an expert group to consider how to incorporate AR issues into regulations governing the registration and use of antimicrobials and antibiotic pesticides.

- The AVMA requests a representative from the veterinary profession be included in the expert group when projects are initiated.

Action Item 63 – Support demonstration projects to evaluate comprehensive strategies that use multiple interventions to promote appropriate drug use and reduce infection rates.

Research
Action Item 77 – Encourage basic and clinical research in support of the development and appropriate use of vaccines in human and veterinary medicine in partnership with academia and the private sector.

Action Item 78 – Encourage basic and clinical research in support of novel approaches to preventing or treating infections with resistant organisms that occur in humans and animals by partnering with academia and the private sector.

Product Development
Action Item 80 – Identify ways (e.g. financial and/or other incentives or investments) to promote the development and/or appropriate use of priority AR products, such as novel compounds and approaches, for human and veterinary medicine for which market incentives are inadequate.

- In veterinary medicine, market incentives for product development are severely lacking. No current projects identify ways to promote development of priority products, or novel compounds and approaches for veterinary medicine.

Action Item 83 – In consultation with stakeholders and expert consultants, identify ways to promote the development of new and alternative treatments and the improved use of existing therapies that are unlikely to stimulate resistance to drugs in human medicine.

- The AVMA continues to advocate for the use of new and existing products that are not likely to impact antimicrobial resistance in human populations. We are disappointed that only a single new antimicrobial drug has been developed specifically for veterinary use since nearly all antimicrobials have a human equivalent and that no projects have currently been identified through the Action Plan to continue this effort.

Action Item 84 – Streamline the regulatory and approval process for veterinary antimicrobial drugs and related products that are unlikely, now or in the future, to result in transfer of antimicrobial resistance to humans.
Action Items in progress that require additional efforts and funds:

**Surveillance**

Action item 2 – With partners, design and implement a national AR surveillance plan

Action Item 3 – Develop standards and technologies

Action Item 4 – To address additional surveillance issues unique to AR

- While post market surveillance for the development of resistance to critical antimicrobials used in veterinary medicine is underway, the surveillance has not been linked to specific drug use, and criteria are not available to allow a prompt response by the profession to changes in trends that may indicate a finding of increased resistance.
- Project Title: Characterization of Antimicrobial Drug Use on Swine, Dairy, and Cow-Calf Operations –
  - This project is likely best suited for Action Item 5
  - Data regarding antimicrobial drug use in veterinary medicine are still lacking in many respects. Although some data on use are collected through the USDA National Animal Health Monitoring system (NAHMS) program, the data do not clearly elucidate usage patterns (what antimicrobials are used, when they are used, or how much is used). Review of NAHMS data would suggest that a more robust data collection system is needed.

Action Item 17 – Expand and enhance coordination of surveillance for drug resistance in enteric bacteria in sick and healthy humans and in sick and healthy animals on farms, at slaughter, and at retail.

- The AVMA believes that the availability of data from sick and healthy individuals, including pathogenic and non-pathogen organisms, is essential for monitoring the transmission of resistant infections and assess the effectiveness of prevention measures.

Action Item 19 – Conduct pilot studies to assess the extent of environmental contamination by antimicrobial residues and drug resistant organisms that enter the soil and water from human and animal wastes.

- A pilot study is underway. The AVMA encourages surveillance if contamination is detected as well as further studies to determine impact on human and animal health.

**Prevention and Control**

Action Item 25 – Conduct a public health education program to promote appropriate antimicrobial use as a national priority.

- Many “Get Smart” programs have been funded and successfully implemented. The AVMA supports the concept of these programs, yet we believe that the “Get Smart on the Farm” program has unique content and therefore requires a collaborative effort and further input from the veterinary community.

Action Item 45 – Support ongoing public health education campaigns on food safety, such as FDA and USDA’s Fight Bac program, whose aims are to educate food producers, suppliers, retailers, and consumers about food safety practices that reduce foodborne infections (including AR infections)

- These campaigns have been successful in increasing awareness and educating the general public about food safety practices. The AVMA is pleased that there is recognition and emphasis on reductions in foodborne infections that will also reduce AR infections.
Action Item 49 – Evaluate the nature and magnitude of the impact of using various antimicrobial drugs as growth promotants in different species, using current animal husbandry practices. Use this information to assist in risk-benefit assessments of such use.

- The AVMA has consistently advocated for risk-benefit assessments of all antimicrobials that have the potential of impacting human resistance levels. We are disappointed that we have not seen the results of any such assessments that truly consider both risks and benefits. Additionally, only one risk assessment has been conducted (virgiuniycin) and has yet to be concluded.

Action Item 50 – Conduct additional research to further define the effects of using various veterinary drugs on the emergence of resistant bacteria that infect or colonize food animals of different species, using various husbandry practices. Identify risk factors and preventive measures.

- A single project is currently on-going under this action item. We believe that further projects under this action item would assess the associated risk of transmission of AR infections or resistance factors to humans.

Action Item 53 – Evaluate the effect of current food processing and distribution methods on the emergence and spread of drug resistant organisms

- NARMS Retail Food is a valuable program for monitoring prevalence of antimicrobial resistant zoonotic pathogens and commensal organisms among foods of animal origin, yet it does not address the effects of food processing and distribution.

Action Item 55 – Assess the risk of AR emergence and spread due to environmental contamination by antimicrobial wastes or by resistant bacteria in human and animal waste.

- Several projects are underway that appear to be promising.

Action Item 58 – In consultation with stakeholders, refine and implement the proposed FDA framework for approving new antimicrobial drugs for use in food animal production and, when appropriate, for re-evaluating currently approved veterinary antimicrobial drugs.

- AVMA is supportive of the Guidance for Industry #152 (GFI #152) process for approval of new antimicrobials for use in food animals, yet we are disappointed that there has only been one drug that has been re-evaluated by a risk assessment. It is our understanding that the GFI#152 is not an appropriate framework for re-evaluating currently approved drugs and we strongly encourage the development of a new framework for evaluating existing antimicrobials.

Action Item 59 – Strongly encourage involvement of veterinarians in decisions regarding the use of systemic antimicrobial drugs in animals, regardless of the distribution system through which the drug was obtained (e.g. regardless of whether a prescription is required to obtain the drug).

- The Veterinary Antimicrobial Decision Support (VADS) System Project was developed in late 2001, however further development and improvement of the system is hindered by a lack of funding. The AVMA believes that programs such as the VADS program are beneficial to veterinarians to select and use antimicrobials effectively and appropriately.

Research

Action Item 76 – Identify, develop, test, and evaluate new rapid diagnostic methods for human and veterinary uses with partners including academia and the private sector.

- The AVMA appreciates that many diagnostic methods have been developed and the projects are ongoing.
Product Development
Action Item 79 – Create an interagency AR Product Development Working Group to identify and publicize priority public health needs in human and animal medicine for new AR products.

- The AVMA believes that the working group should allow stakeholder input in the process as veterinary medicine has a significant need for new AR products.

While we appreciate the efforts of the Interagency Task Force on this complex issue, we assert that the animal and veterinary components of the plan have been continually underfunded yet are necessary in order to tackle the threat of antimicrobial resistance. We also contend that few of the original 13 Top Priority Action Items have targeted animal health and have yielded results that can mitigate antimicrobial resistance in animals. Finally, other animal health-oriented Action Items still require additional funds and efforts for full implementation.

The AVMA appreciates the opportunity to comment and would like to continue the dialog on this and other important matters. We also would welcome further opportunities to provide our insights and feedback. For further clarification on the AVMA’s comments, please contact Dr. Christine Hoang, at choang@avma.org or 800-248-2862 ext. 6742.

Sincerely,

W. Ron DeHaven, DVM, MBA
Chief Executive Officer, AVMA