ANIMAL HEALTH INSTITUTE

Animal Health Industry Perspective on AMR in Food-Producing Animals

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Presented by: Dr. Richard Carnevale
Vice-President, Regulatory, Scientific and International Affairs
Animal Health Institute

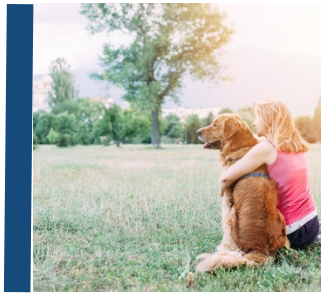
ANIMAL HEALTH INSTITUTE

- A trade association representing major manufacturers of animal health products.
- Currently **15 fully licensed members** and **9 Affiliate members.**
- Multinational companies and smaller biologics manufacturers.
- Represents the majority of R&D investment in animal health products in the U.S.

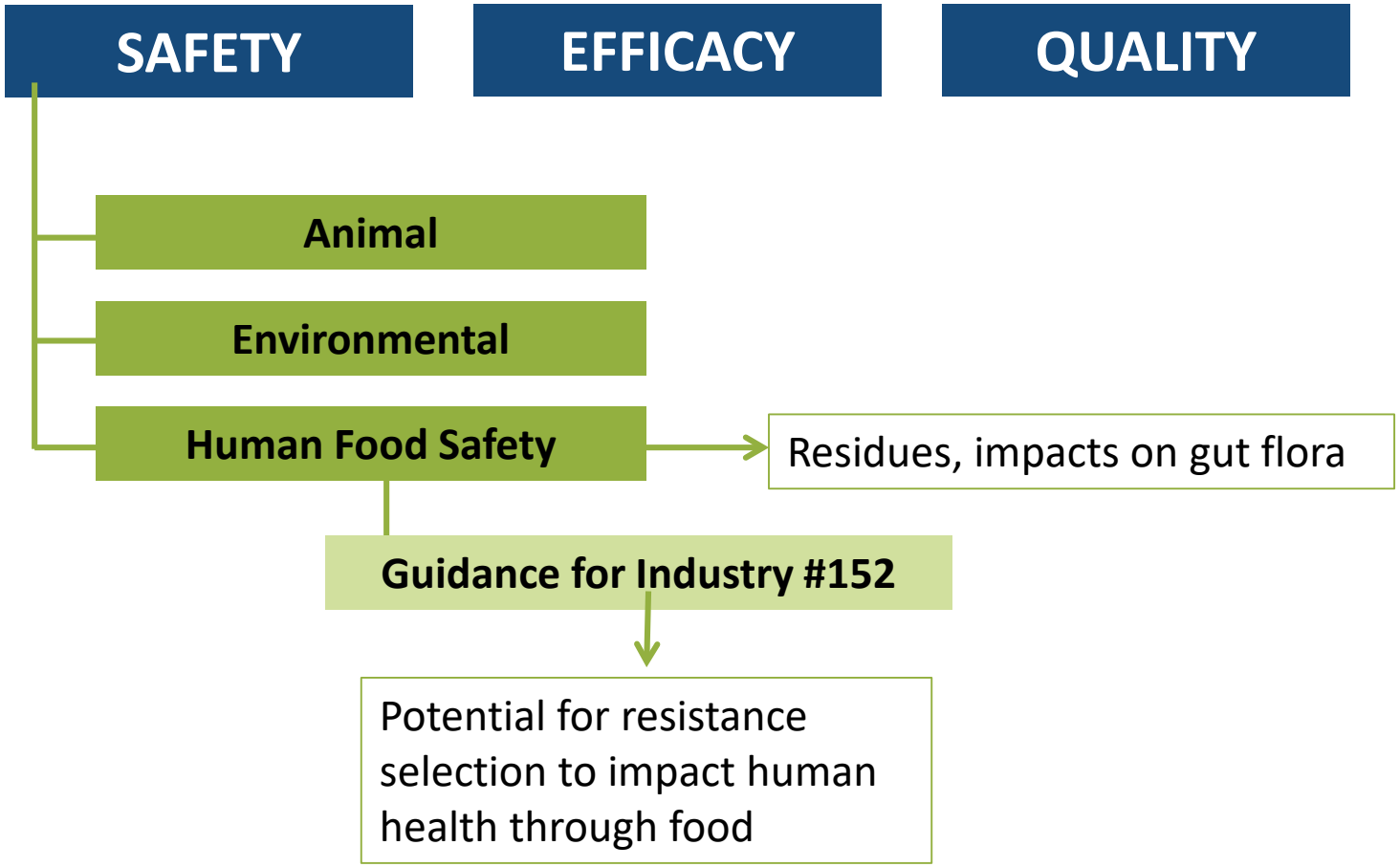
ANIMAL ANTIBIOTIC APPROVALS

- AHI members have always operated under a One Health paradigm:
  - Animal Health
  - Human (Public) Health
  - Environmental Health
- Food and Drug Law requires these three areas to be addressed for all food animal drugs.





FDA APPROVAL PROCESS



EVOLUTION OF AMR REGULATION

1970's	FDA required specific AMR testing on all antibiotics used in feed: – E.coli resistance – Salmonella shedding – Most antibiotics passed the set criteria
1988	All new antibiotics must be labeled as prescription drugs
1996	FD&C Act amended to allow for Veterinary Feed Directives as a form of prescription drugs since no previous legal authority existed for feed additives.

EVOLUTION OF AMR REGULATION

1996	National Antimicrobial Resistance Monitoring System (NARMS) instituted for food borne pathogens in humans, animals and later retail meats.
2003	Guidance for Industry #152 – qualitative assessment required to assess potential selection of resistance in food animals and human health.
2008	FD&C Act amended to require sponsors to report antimicrobial sales data. – 2016 – FDA adds requirement to estimate sales by species.

EVOLUTION OF AMR REGULATION

2012

FDA Guidance for Industry #209 - Judicious Use Recommendations on growth promotion claims for medically important antimicrobials for feed and water.

- All Animal Health Companies committed to implementing the FDA recommendations.
- FDA reports full implementation on January 2017.

GUIDANCE #209

- Stated objectives were to improve judicious use of medically important antibiotics:
  - Eliminate growth promotion
  - Require veterinary supervision
- Objective was not to necessarily cause overall reductions in sales although reductions could result with certain antimicrobial classes.
- Guidance was also not based on specific safety concerns with each antimicrobial class.

PREVENTION AND CONTROL

- FDA maintained these indications for medically important antimicrobials because of animal health and welfare concerns.
- Herd/Flock health is population medicine as opposed to individual treatment.
- Preventing disease is critical in food animals since hundreds to thousands of animals are at risk if there is a disease outbreak:
  - Vaccines
  - Antimicrobials

ANIMAL WELFARE

- Disturbing trend toward promotion of antibiotic free labeling.
- Animals needing treatment diverted to conventional productions lines where antibiotics can be used; if not animals would suffer and die.
- No evidence that antibiotic free labeling means safer food.
- TogetherABX.com seeks to educate consumers on the use and risks of antibiotic use in animals.

MOVING FORWARD

- Antimicrobials are critical to animal, human and public health.
- Reduced use of antimicrobials not necessarily correlated with decrease in resistance.
  - NARMS shows 85% of all human Salmonella susceptible to all tested antimicrobials
  - Recent Scottish publication concludes:

> *"….curtailing the volume of antibiotics consumed by food animals has, as a stand alone measure, little impact on the level of resistance in humans."*

MOVING FORWARD

- New restrictions on antimicrobials must be based on scientific data not perceptions or market pressures.
- Animal health needs new vaccines, antimicrobials or alternatives – PACCARB WG on incentives.
- Sales data is not a substitute for actual use data to improve judicious use – AHI supports funding of the USDA/FDA CARB plan to collect on farm data.