

## **Jeff Simmons Remarks to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria**

Mr. Chairman and distinguished members of the council, thank you for the opportunity to participate in today's meeting. The emergence of antimicrobial resistance is one of the most serious issues facing our public and animal health systems.

Elanco, a division of Eli Lilly and Company, is a global animal health company that develops and markets a wide range of animal medicines, including antibiotics, vaccines, enzymes, and therapeutics for livestock and pets.

The animal health industry believes it's our responsibility to help farmers produce enough safe, affordable food in a sustainable manner while safeguarding animal health, welfare and food safety. We also have a responsibility to help keep animals healthy, and to treat sick animals while balancing the long-term effectiveness of antibiotics for animal and human use.

Healthy animals mitigate antimicrobial resistance potential, limit potential for zoonotic disease spread, support livelihoods, and provide nutrient-rich protein to support human health. Protein matters more than ever. I believe animal protein – meat, milk and eggs – will be the #1 food segment in the coming decades and will have the greatest impact on improving human health – from physical and cognitive development in the first 1,000 days of a child to obesity to maintaining muscle mass and bone density in an increasing elderly population. With an estimated 60 percent increase in demand for meat, milk and eggs in the coming decades<sup>1</sup>, environmental sustainability will be key as farmers work to meet that demand while using fewer of the earth's resources.

The health of animals is inextricably linked to that of people and the environment. To separate one from the rest would be like pulling one string of an intricate tapestry – it would unravel.

Elanco is committed to antibiotic stewardship and engaging in collectively shaping science-based recommendations on responsible use. Two years ago leaders from across human and animal health gathered at the White House to further antibiotic stewardship. Building on the collaboration created at

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<sup>1</sup> Food and Agriculture Organization of the United Nations. Feeding nine billion in 2050. 12 April 2013.  
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that event, Elanco committed to an 8-point plan to help combat antibiotic resistance. We're ahead of schedule on these efforts, including:

- Growth promotion: Completing 93 label changes to remove growth promotion from our portfolio of medically important antibiotics, not just in the U.S., but around the world.
- Veterinary Oversight: Completing submission of 67 labels to move medically important molecules from over-the-counter use to the oversight of a veterinarian in the United States and other countries where veterinary infrastructure exists.
- Analytics: Bringing the largest analytic capability to producers helping identify emerging health and welfare issues through data.
- Innovation: Making a significant investment in R&D to bring new animal-only antibiotics and create alternatives. Since the White House forum, Elanco has brought two new animal-only antibiotics to the poultry and pork industries. We've launched four antibiotic alternatives, including vaccines, enzymes and a first-of-its-kind protein. Imrestor helps support natural function of a dairy cow's immune system, reducing incidence of clinical mastitis – the primary reason antibiotics are used in the dairy industry today.

Elanco is not alone in this effort. The entire animal health industry has supported modifications to product labels that led to two major changes in the United States.

- First, narrowing uses of medically important antimicrobial drugs in food-producing animals to only fight disease; and
- Two, ensuring these products are only used under the oversight of a veterinarian.

By January 1, 2017 a total of 292 product labels from 26 companies were either changed or withdrawn. As a result, medically-important antibiotics in animal feed and water are only used to fight disease and under the direction of a veterinarian.

SLIDE: Priorities Declaration

Further, a first-of-its-kind One Health Summit was held in September bringing together more than 200 leaders from the global food industry, NGOs, government and other stakeholders to collectively address this challenge. As an outcome, about 40 CEOs from some of the largest meat and dairy companies in the world signed a commitment to focus on five priority areas. You will notice these priorities align with the

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National Action Plan for Combating Antibiotic Resistant Bacteria. As you well know, there is no simple, fast answer, but the work is ongoing and there is commitment to continued progress.

As we look toward the future, we believe there are three areas that can have the greatest impact on combating antimicrobial resistance.

- 1) The Right Metrics
- 2) The Right Regulatory Pathway
- 3) The Right labels

### The Right Metrics

The metrics used to evaluate progress in combating antibiotic resistant infections in people and animals must be more comprehensive and focused on the desired outcomes. The goal is to reduce antibiotic resistant infections in people by ensuring responsible antibiotic use in all settings. Yet the main measure we're tracking today is volume of use. Responsible use does not mean eliminating use. As we're learning with the increasing move toward poultry raised without antibiotics, eliminating antibiotics does not eliminate disease. According to the OIE - World Organisation for Animal Health, there are 18 pathogens in pork and poultry without viable treatment alternatives beyond antibiotics today.<sup>2</sup>

Measuring antibiotic use volume does not consider overall fluctuations in animal numbers, prescribing behaviors, disease pressure, feed quality, weather, and the health of the animals. With 60 percent more animal protein needed in the next few decades, animal numbers will certainly climb. In poultry alone analysis indicates we'll need at least 40 billion more birds globally to meet demand by 2050.<sup>3</sup>

Most importantly, today's metrics don't capture data on the presence, frequency, and distribution of antibiotic resistant bacteria – either naturally occurring or caused from selection. Instead, we would be better served to focus on prescribing behavior and eliminating inappropriate prescriptions of medically important antibiotics in animals – just as CDC is focused on eliminating inappropriate prescriptions in hospitals and outpatient settings.

Agriculture has shown we are committed to taking action on this critical issue. But my biggest concern is that no matter what we do in agriculture, it may never be enough to make a difference in the fight

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<sup>2</sup> Erlacher–Vindel, E. Prioritisation of Diseases for which Vaccines Could Reduce Antimicrobial Use in Animals. 2nd International Symposium on Alternative to Antibiotics: Challenges & Solutions in Animal Production. Dec. 2016.

<sup>3</sup> Knapp, J., Cady, R. 2013 Food Forward Report. Elanco Animal Health. 2013. Data on File.

against resistance. Even if we were to completely eliminate all use of antibiotics in animal agriculture, it would not have a meaningful impact on resistance of human concern. Of the 18 major antibiotic resistance threats the CDC tracks, only two, campylobacter and non-typhoidal Salmonella, are associated with animals<sup>4</sup>. Reports show resistance for these pathogens is trending the right direction with prevalence of both reaching all-time lows in the most recent NARMS reports.

The most serious pathogens are not related to antibiotics used in food animals. A repeated use of amoxicillin for an ear infection in people is likely to have a greater impact on resistance of human significance than current products fed in a large feedyard. A new study published in the UK last month noted, “Our results suggest that, for a wide range of scenarios, curtailing the volume of antibiotics consumed by food animals has, as a standalone measure, little impact on the level of resistance in humans.<sup>6</sup>”

However, untreated sick animals would likely cause a much greater human health risk.

#### The Right Regulatory Pathway

Delivering new alternatives to antibiotics creates an opportunity to reduce the need for medically important antibiotics while addressing animal health challenges. In the past year, there were 15 new product submissions from the animal health industry and new study protocol submissions have been trending steadily upward over past few years. We must be able to bring novel therapeutics with a unique modes of action to market in a timely manner. To be clear, we are not asking for adjustments in safety evaluation – this is about efficacy.

By contrast, human biopharmaceutical companies have several pathways for breakthrough technologies, expedited approvals, and similar abbreviations in the efficacy evaluation of a new medicine to bring new products to market in a safe, expedient way. In fact, the priority approval time for human pharma products dropped by an average of 16 months due to reduced review and clinical development time. A parallel approach in animal health could speed the availability of these alternatives, reducing the use of medically important antibiotics in the future.

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<sup>4</sup>CDC: <http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>

<sup>5</sup>2014 Integrated NARMS Report

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059103.htm>

<sup>6</sup> B. A. D. van Bunnik, M. E. J. Woolhouse. “Modelling the impact of curtailing antibiotic usage in food animals on antibiotic resistance in humans.” 5 April 2017.

If a product's safety is proven and it can reduce medically-important antibiotic use, shouldn't we be looking at an accelerated review?

### The Right Labels

Consumers increasingly have questions about how their food is grown, and we have a responsibility to increase the availability of accurate information about food choices to help consumers make informed decisions. Marketing and labels that drive brand differentiation also create confusion about what's safe and healthy.

Today, two-thirds of shoppers who buy meat and poultry labeled "Raised Without Antibiotics" believe they are helping to reduce on-farm use of the antibiotics needed by people, while 70 percent believe they are supporting better animal welfare<sup>7</sup>.

### SLIDE: Impact of Removing Medicine

However, data tells a different story. By removing all medicines, more animals experience clinical illness. A Canadian government-funded study shows that 27 percent of animals in an optimized antibiotic-free system experienced clinical illness, in this case necrotic enteritis<sup>8</sup>. This compares with less than 1 percent of animals in a system that utilizes ionophores, which are a non-medically important antibiotics with no application to human medicine.

### SLIDE: Analysis of RWA

Reports indicate between 5 and 25 percent of barns Raised Without Antibiotics will break with disease. If all U.S. chicken production transitioned to Raised Without Antibiotics, conservatively assuming 5% of barns require treatment for necrotic enteritis, as many as 320 million additional birds would be treated<sup>9</sup>. That's a calculated potential increase of 57 tons of medically important antibiotics each year in the

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<sup>7</sup> Consumer Reports (CR). 2012. "Meat on Drugs- Consumer Opinion Survey," pages 1-25. 6/2012. [https://www.consumerreports.org/content/dam/cro/news\\_articles/health/CR%20Meat%20On%20Drugs%20Report%2007-12b.pdf](https://www.consumerreports.org/content/dam/cro/news_articles/health/CR%20Meat%20On%20Drugs%20Report%2007-12b.pdf)

<sup>8</sup> Gaucher M-I, et al. "Impact of a drug-free program on broiler chicken growth performances, gut health, *Clostridium perfringens* and *Campylobacter jejuni* occurrences at the farm level." *Poult Sci*. 2015 August;94(8):1791-1801.

<sup>9</sup> Salois, M., Heskett, E. "Raised without antibiotics can lead to more use of medically important antibiotics."

poultry industry alone!<sup>10</sup> “Raised Without Antibiotics” production practices appear to be exacerbating potential for antibiotic resistance.

To conclude, thank you again for the opportunity to share this perspective. You have a very important role in providing advice and recommendations on plans, programs, and policies to help combat antibiotic resistant bacteria. I commend you for your inclusion of the One Health approach in your recommendations and encourage you to continue to do so.

As you move forward in your goal to increase responsible antibiotic use, I encourage you to keep in context agriculture’s role in this challenge and commitment to progressing solutions. This is about resistance, not tons of use. Eliminating use does not eliminate disease. Untreated, sick animals could bring a far greater public health risk. We need the right metrics to ensure we’re progressing on the desired outcomes without unintended consequences.

We need regulatory pathways that accelerate review for safe, effective new alternatives. Finally, we need labeling that doesn’t confuse consumers and create the wrong outcomes in the barns and fields of American agriculture.

Addressing these challenges is bigger than any one entity. It will require participants across the food chain and healthcare systems – farmers, veterinarians, doctors, NGOs, the public and private sectors – to work together. This is the only way we can solve a challenge of this size and urgency. It’s our responsibility for people today and for the generations to come.

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<sup>10</sup> Salois, M., Heskett, E. “Raised without antibiotics can lead to more use of medically important antibiotics.” GCAAFFNON00208