

# For the Record

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Straight talk about antibiotic use in food animal production presented by ALPHARMA Inc., Animal Health

## IF SCIENTIFIC DEBATE EQUALS HERESY, TRUTH IS THE VICTIM

More than 350 groups officially endorse the **current federal bill** to limit antibiotic use in food production, as activists like to remind the news media—often. Even once you cull out the not-particularly-scientific members of that list, you still wind up with nearly **200 bona-fide medical organizations** whose credentials are hard to argue with, including the American Medical Association. How dare a farmer dispute the word of pediatricians and brain surgeons?

In that question is a chilling example of how politics is today beginning to corrupt the integrity of scientific research, as Harvard-trained doctor turned novelist and film maker **Michael Crichton** believes. True science is not a democratic process subject to majority rule. Science is a search, **Crichton says**, a process of discovery conducted over long periods by thousands of individuals, guided by objective measures that can be tested, reviewed and confirmed. When the numbers that matter become less about facts and statistics and more about the number of **colleagues who agree** with you, the dissenting voices

we rely upon to advance scientific debate and knowledge risk becoming **heretics and outcasts**. Science suffers for it.

When a **landmark review** of 20 years' worth of research into the question of antibiotics in food production was released recently, some people—some with MDs and PhDs after their names—were **quick to attack** the funding, assumptions and allegiances of the 18 microbiologists and veterinarians who conducted it, with little or **no meaningful criticism of the science**.

Science endangers truth when it defers to politics, Crichton believes. "I'm concerned that science, having ascended to a phenomenal position of power within our society, has provided a temptation for some highly intelligent individuals to join in the political fray, where they really don't belong, where they do it really badly, and where they don't acknowledge they are **damaging science** as an enterprise," he says. "Science needs to be kept separate from politics."



### Also in this issue

- The food system is too complex to just assume simple solutions like banning antibiotics will help prevent diseases in people, the new IFT report says.
- If the risks are uncertain, why not err on the side of better safe than sorry? Some cautionary tales of precautionary over-reaction.
- Don't like the science? Then work to disprove it. But don't attack the scientists, says IFT.

### Case in point: reining in two decades of dioxin scare

Motivated in part by publicity over the alleged effects of the herbicide Agent Orange in Vietnam veterans, the U.S. **Environmental Protection Agency** in 1985 first labeled its active ingredient, **dioxin**, a "probable" cause of environmental human cancer. A byproduct of industrial and natural burning, dioxin is found virtually everywhere at low levels, including our bodies. By 2000, EPA had turned up the volume on its assessment of dioxin's cancer potential, indicating the agency was on a track that could have mandated a maximum permitted daily exposure as much as a thousand times under the average individual's daily intake.

Spurred by concerns the agency's un-reviewed assessment was overstating those risks, Congress requested EPA have its homework checked by the **National Academy of Sciences (NAS)**. EPA ignored the request until Congress finally demanded it as a condition for continuing to fund the agency.

That review of the original EPA assessment, released this summer, took EPA to task for the method it used in making its conclusions. Although it doesn't deny dioxin is toxic, the **NAS criticized EPA** for how it determined dioxin's contribution to human cancer. NAS in effect told EPA that when it comes to estimating cancer risk, you can't always assume there's a one-to-one comparison between the cancer-causing dose in lab rats and the dose in humans. Furthermore, EPA wasn't free to simply choose the model it wanted to use and ignore others less favorable to its desired outcome, NAS said.

The humbling of a too-powerful EPA by scientific review has been called "a teachable moment" by the more polite observers of government policy. The case study demonstrates the checks and balances of open scientific debate and peer review are a critical part of making sure science is used—and not misused—for policy-making.

### For the record...

Political decisions about food-animal antibiotics may actually work against the goal of protecting human health, a new review of 20 years of research says.

# RESEARCH REVIEW URGES CALM DELIBERATION

Over five years ago, the prestigious *New England Journal of Medicine* lent its reputation to a series of studies and a guest editorial proclaiming the “smoking gun” had at last been found to blame food-animal antibiotic use for cases of human disease that couldn’t be treated with some antibiotics. Dismissing the body of research that contradicted its conclusion, as well as some weaknesses in its own studies, the editorial proclaimed the time

had arrived to act on the proof the Journal submitted, and to ban many uses of animal antibiotics. Many have borrowed that credibility since to push for an end to the practice.

Meanwhile, other—perhaps more healthily skeptical—scientists ignored the Journal’s advice, laboring on to help understand why, where and how certain bacteria adapt to antibiotics. While their colleagues continue to editorialize about a body of evidence and a “simple truth” that food animal

antibiotics cause human drug failures, others appreciate the value in the century-old observation: The pure and simple truth is rarely pure and it’s never simple.

This summer, a 22,000-member nonprofit scientific and educational society for scientists, technologists and other pro-

fessionals in the food industry, universities and government published a 183-page review of much of that research. Compiled by 18 internationally known doctors of philosophy and veterinary medicine, a third of them microbiologists, the Institute of Food Technologists’ *Antimicrobial Resistance: Implications for the Food System* reviews more than 750 previously published papers that span two decades. Some of the panel’s conclusions include:

■ **SIMPLE, QUICK FIXES RISK FAILURE.** How resistance transfers is a complex scientific phenomenon that takes place in an equally complex system, the authors caution. That means finding similar genes for resistance shared by bacteria in food animals and humans says nothing about how the genes got there, for instance. Failure to respect the complexity of the system can lead to decisions that are “draconian and without predictable results,” the panel says. Case in point: Europe, where regulating away farmers’ ability to use antibiotics preventively may have reduced the overall use of antibiotics, but it also caused more animal disease and increased the use of important human antibiotics to treat sick animals.

**‘Failure to respect the complexity of the system can lead to draconian and unpredictable results.’**

## Shouldn’t we just agree to be better safe than sorry? Not necessarily

Even the most strident proponents of a ban on agricultural antibiotics concede it’s impossible to directly measure the risk of harm they pose to human health.

It’s in the solution to that uncertainty where the sides part company. Where some see lack of scientific evidence as reason to presume safety, others see that same lack of proof as evidence that we must err on the side of precaution.

“Surely [it’s] a small price to pay to help keep our life-saving antibiotics working,” said representatives of the animal-rights and anti-technology activist groups Food Animal Concerns Trust and the Institute for Agriculture and Trade Policy in a **canned criticism** of the IFT report printed by Omaha and Chicago’s daily newspapers.

Unfortunately, that prejudice toward rash action often carries its own set of costs—in dollars and human suffering:

■ Because of the way FDA approves and regulates a drug—basing approval only on evidence that it presents no substantial risk of harm or ineffectiveness while disregarding any risk that people will get sick or die if a drug isn’t available—FDA inherently errs on the

side of regulating cautiously.

The agency is so cautious, in fact, that it scores a net *loss* in terms of lives saved, **according to a research review** by two economists at California’s Independent Institute, a non-partisan, free-market think tank. In other words, its precautionary regulation kills or harms more people than it helps.

For example, a 1985 analysis comparing **death rates before and after** new drugs were introduced here, as well as against countries where those drugs were currently approved while awaiting U.S. approval, estimated that FDA’s delay in approving new drugs claimed anywhere from 21,000 to 120,000 lives per decade. And it’s believed a greater number of people get sick and die because the **\$802 million price** which the Tufts Center for the Study of Drug Development estimates FDA regulation imposes on the average new drug prices most prospects out of ever being developed.

■ Environmentalists often point to the banning of the pesticide DDT in reaction to publication of Rachel Carson’s 1962 *Silent Spring* as one of the movement’s shining moments in rallying

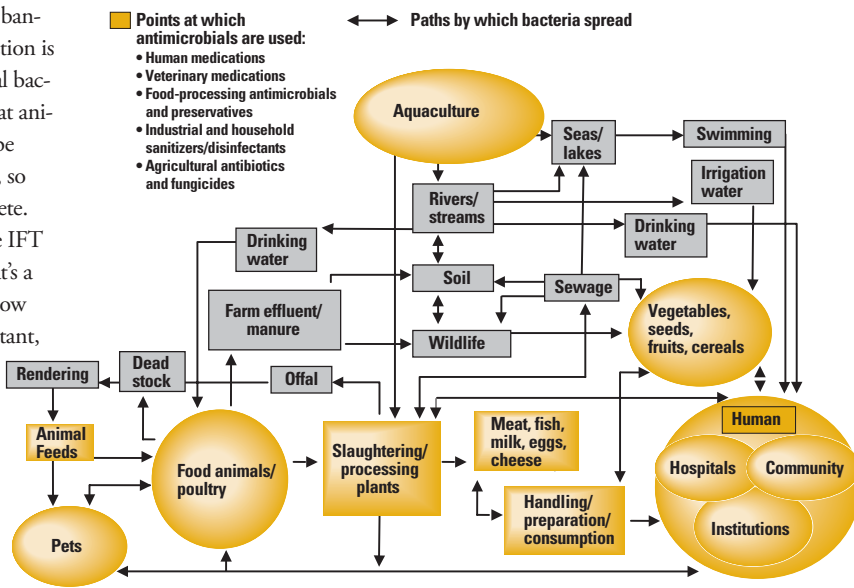
public pressure to force precautionary policy. Yet the eventual loss of that safe, effective and cheap pesticide—as a precaution against harming reproduction in migrating eagles—has now allowed a **global resurrection of diseases** like malaria, which had been nearly eradicated by it. The World Health Organization now reports up to a half billion new cases every year. The equivalent of **seven jetliners full of poor Africans** die daily as a result, says one pro-DDT activist.

■ Studies are showing antibiotics help control food-borne disease. Studies by University of Georgia microbiologist Scott Russell have demonstrated that subclinical disease level in chickens—which can be damped by low-level antibiotic feeding—significantly impacts contamination with illness-causing *Salmonella* and *Campylobacter* at processing. Other work has conservatively estimated that at least 40,000 sick days are prevented yearly by the continuous use of only one antibiotic in chicken flocks. Ending use of those compounds, the IFT report concluded, wouldn’t come free. It would cause a real and measurable increase in human disease.

## A complex web of resistant organisms' spread defies simplistic solutions

Activists argue that the logic of banning antibiotics in food production is simple: Antibiotics cause animal bacteria to grow resistant, people eat animals, people get sick and can't be treated with human antibiotics, so the chain of causation is complete. Unfortunately, according to the IFT study of antimicrobial data, that's a grossly oversimplified view of how bacteria, resistant and non-resistant, flow through the overall food chain. Any touch point between points creates the potential to transmit resistant bacteria or their genetic material in either direction.

Source: Adapted from Institute of Food Technologists. *Antimicrobial Resistance: Implications for the Food System*, 2006.



### For the Record Web Bonus

Link to the IFT Expert Panel report and review the current science for yourself, available through [www.alphaaah.com](http://www.alphaaah.com).

### ■ WE'RE FAR FROM ANY "SMOKING GUN."

Granted, some evidence points to a human health threat related to animal antibiotic use, the study authors write. But it does not prove that risk exists. The controversy feeds and grows off our inability to directly measure cold, hard facts that tell us how much, if any, the practice contributes to human illness. At the same time, we do know of one area where a search for a smoking gun has potential to reward scientists with proof: Prior human exposure to antibiotics has been proven to be the greatest risk factor for acquiring an infection with antibiotic-resistant bacteria, notes University of Georgia microbiologist Michael P. Doyle, chairman of the IFT panel. That means control rightly begins in the hospital and pediatrician's office, not the farm or packing plant.

### ■ SCIENTIFIC RISK ASSESSMENT IS CRITICAL.

The panel cautions that the currently fashionable inclination to forbid an antibiotic based simply on how it's used in animals—whether for routine disease prevention, growth promotion or "non-therapeutic" use—is counterproductive. Such important decisions must be based on the results of a **scientific risk assessment**. Logical and methodical risk assessments help correct breakdowns in the entire food system, which IFT is taking responsibility for finding and fixing. For example, Doyle points out: The risk factors that predispose people to a case of antibiotic-resistant food poisoning tend to be the very same factors that predispose them to a case of food poisoning that's treatable. Preoccupation with the antibiotic aspect can thus distract from the bigger issue.

Another case illustrating the need for logical risk assessment: The study notes that although **organic production** is less likely to contribute to antibiotic resistance, it's potentially more likely to contribute to contamination with bacteria in general, because it prohibits antibiotics, raises animals

outdoors, keeps them around longer, and processes them at smaller, less technological plants.

### ■ YOU CAN'T IGNORE ANTIBIOTICS' BENEFITS.

Decisions about the risk of antibiotic use cannot be made without also considering the benefits; otherwise, people would never drive cars for fear of accident. Evidence shows eliminating antibiotics for any purpose but treating disease increases disease among animals, increases the need to treat animals—thus increasing the risk of creating resistant bacteria that could potentially infect humans—and increases the amount of bacteria like *Salmonella* on animal carcasses when they go to processing.

Ironically, the report notes, the hostile climate toward some uses of animal antibiotics may be discouraging the development of new drugs to combat the resistance that originally spurred the attention on animal antibiotics in the first place. It's a cycle that's threatening to leave us with fewer drugs as bacteria continue to grow resistant, Doyle says.

■ **THERE'S STILL MUCH WE DON'T KNOW.** A lot of gaps exist in our understanding about antibiotic resistance, the study points out, including:

- Where resistant organisms tend to pool in the environment
- How easily those environmental genes transfer to bacteria that colonize the human intestinal tract
- Whether antibiotic resistance in foodborne bacteria make them capable of causing more serious disease
- Precisely how antibiotics improve animal performance, with an eye toward adapting those mechanisms.

Answering some or all of those questions would help solve much of the controversy that now exists. But it's no small task. "The scope of information needed is enormous," Doyle says.

We don't need less science in this issue, IFT advises. We need more.

### For the record...

A recent review of 20 years worth of science warns that blanket bans on animal antibiotics could be rash, ineffective in protecting human health and potentially harmful.

## For the record...

Rather than issue false claims and personal attacks, critics of antibiotic use should step up and join those of us working toward meaningful solutions.

## For the Record,

sponsored by a grant from ALPHARMA Inc., Animal Health, is designed to help unite the industry and provide a unified, rational message on behalf of producers whose freedom to use safe, effective, economical production methods is at stake. Working together, we can set the record straight on antibiotics.

Do you have questions or comments? E-mail [Steve Kopperud](mailto:Steve.Kopperud@skopperud.com) at [skopperud@skopperud.com](mailto:skopperud@skopperud.com) or [editor Mike Smith](mailto:editor.Mike.Smith@CustomMedia@Food360.com) at [CustomMedia@Food360.com](mailto:CustomMedia@Food360.com). Want to read past issues or link to more information on this issue? [Visit us online](http://www.alpharmaah.com) at [www.alpharmaah.com](http://www.alpharmaah.com).

# FALSE CLAIMS DO NOTHING TO ADVANCE SCIENCE

FROM THE IFT OFFICE OF SCIENCE, COMMUNICATIONS AND GOVERNMENT RELATIONS

Claims that human health is threatened by non-therapeutic antibiotic treatments of animals raised for food are in direct conflict with reliable scientific documentation. The IFT Expert Report *Antimicrobial Resistance: Implications For The Food System*, contradicts the false claims, vague information and erroneous statements being made in an attempt to discount scientific consensus.

Such claims ignore the evidence that shows eliminating the use of antibiotics for non-therapeutic reasons has resulted in increased disease among animals and increased antibiotic use for disease treatment, thus increasing the risk of exposure to resistant bacteria and, in turn, increasing the threat to human health. They also fail to take into account that low doses of antibiotics help to reduce from food animal carcasses the occurrence of bacteria that cause human illness (such as *Salmonella*). That is a significant human health benefit to antibiotic use.

Interventions that reduce the prevalence of foodborne pathogens also reduce the prevalence of pathogens that are resistant to antibiotics.

Applying these many interventions to control foodborne pathogens in general, rather than focusing on antibiotic-resistant microbes specifically, would have the greatest impact in reducing foodborne illnesses.

The expert panel of microbiologists, veterinarians and other scientists commissioned by, and working independent from, IFT, urge their scientific peers, government regulatory agencies, and the food production and manufacturing sectors here and abroad to actively acquire much needed data in order to make the most informed decisions possible regarding the future of food production systems and their impact on food safety.

The complexity of antibiotic resistance precludes simple solutions and single approaches. Effective food safety systems integrate science and risk analysis at all levels. Acquired resistance

is a complex scientific phenomenon that takes place within a larger system. It is critical to recognize this bigger picture when considering policies. A thorough risk assessment can provide the framework for that big picture.

Solutions cannot be based on hopes and guessing no matter how loudly trumpeted. It serves no reasonable purpose to the world's population to demand drastic change on the simple hope that

improvements to human health will result. The tendency for resistance varies with bacterium, the antibiotic and usage pattern. It varies among the same areas as applied to human medicine. Policies regarding antibiotic use in food animals should be developed through a case-by-case, science-based risk assessment.

Rather than issuing bogus information, unsubstantiated claims, and personal attacks, those with single viewpoints would better serve this complex issue, public health, food system needs, and society at-large by working in concert with scientific, regulatory, and advocacy communities for the benefit of everyone.

IFT is a professional association of scientists, technologists and others. Panel chairman Michael Doyle is an internationally respected food microbiologist who has dedicated immense effort to advance food safety. IFT-commissioned Expert Reports utilize expertise within and outside IFT to purposefully and comprehensively address critical issues and bring sound scientific analysis to topics that often can be clouded by hyperbole and myth. Any claims contrary to these are false.



University of Georgia

IFT Expert Panel Chair Michael P.

Doyle faced some public criticism for the report, as well as his work in the food industry. This **in spite of his credentials** as director of the Center for Food Safety at the University of Georgia and authorship of more than 200 papers and several books. "We were just trying to bring some balance to the discussion," Doyle says.

**'Solutions cannot be based on hopes and guessing, no matter how loudly trumpeted.'**

## MORE OVERSIGHT OF FEDERAL RISK REVIEW?

The White House's accounting arm, the **Office of Management and Budget**, has issued a new proposed policy to try to better oversee the risk-assessment information the federal government generates for use with the public, in order to try to improve its objectivity, usefulness, integrity and quality. OMB has expressed a need for consistent guidance when it comes to judging the **routine risk assessments** agencies generate in order to prioritize funding and spending, manage risk and inform the public of those risks.

OMB has asked for technical assistance from the **National Academy of Sciences** and will organize and accept public comment, as well as conduct public workshops, to discuss the issue.

Noting the reality that animal health is highly regulated by several federal agencies and the recent increase in require-

ments FDA is applying to new and approved animal antibiotics, the Animal Health Institute welcomed the new proposal—as far as it goes. **AHI is particularly concerned** that OMB set some standards for the less quantitative and more qualitative "influential" analyses FDA is beginning to subject **animal drugs** to regarding their perceived risk when it comes to contributing to antibiotic resistance.

AHI suggests such softer, more subjective risk ratings need to have their underlying assumptions that go into the qualitative analysis clearly stated, reviewed and justified. The methods used to calculate qualitative risk ratings should also be subject to hard scrutiny and described completely. Any known limitations in the method also need to be spelled out clearly for reviewers and the public, as well, the group urges.