

Introduction

Resistance to antibiotics is hardly a new problem; ever since the advent of penicillin and other antibiotics more than 50 years ago defiant strains of bacteria have emerged.¹ The harrowing aspect is that now almost every human pathogen treated with antibiotics is showing resistance, and many doctors fear that this will only be the tip of the iceberg.² After all, every time any antibiotic is used, while it may kill the majority of the bacteria the drug was intended to destroy, there is a likelihood that a few germs will remain, surviving because of their resistant traits or their ability to mutate and become resistant to antibiotics. Once created, these resistant genes can multiply quickly, creating new strains of bacteria that could result in the patient's next infection failing to respond to the previously administered antibiotic.³ In fact, bacteria can reproduce about every twenty minutes, meaning resistance is quickly spread, and the resistant strand eventually becomes the dominant strand of that species.⁴

Many of these concerns result from the widespread overuse and overprescription of antibiotics.⁵ Many patients and physicians are unaware of the possible

¹See Tamar Nordenberg, *Miracle Drugs v. Superbugs*, FDA CONSUMER, Nov. 1998, at 22.

²Id. Linda Tollefson, director of surveillance and compliance in FDA's Center for Veterinary Medicine, said, "You're dealing with living microbes that have shown an incredible ability to accommodate antibiotics and come out winning. We have no idea what they are going to do next. Our fear is that we're seeing the tip of the iceberg."

³See id.

⁴See Scott B. Markow, *Penetrating the Walls of Drug-Resistant Bacteria: A Statutory Prescription to Combat Antibiotic Misuse*, 87 GEO. L.J. 531 (1998).

⁵See Michael Misocky, *The Epidemic of Antibiotic Resistance: A Legal Remedy to Eradicate the "Bugs" in the Treatment of Infectious Diseases*, 30 AKRON L. REV. 733, 734 (1997).

harm caused by overuse of antibiotics, and even when the doctor is aware of the risk antibiotics are often prescribed to placate the patient who views antibiotics as a panacea.⁶ Out of the 150 million prescriptions for antibiotics each year, one expert comments that 50% of these are considered inappropriate prescriptions.⁷ Such misuse of antibiotics has already resulted in new strains of previously believed easily controlled diseases, such as tuberculosis, dysentery, and malaria.⁸ Sadly, this is far from just a United States problem, since in many parts of the world, such as Mexico, South America, and Southeast Asia, antibiotics are available over-the-counter.⁹ It is this constant overuse through the years of antibiotics that have some expressing concern of a plausible “superbug”; a micro-organism effectively resistant to all known forms of antibiotics.¹⁰ If one views a “superbug” as a far-fetched notion, just consider some examples. In 1941 virtually every case of the contagious killer *Staphylococcus aureus* was curable with penicillin, while today fewer than 5% of these cases are treatable with penicillin.¹¹ Further consider that today there are three life-threatening bacteria strains (*Enterococcus faecalis*, *Mycobacterium tuberculosis*, and *Pseudomonas aeruginosa*) which are resistant to all current antibiotics.¹² Scientists still do not entirely understand the possibilities of bacterial reproduction, mutation, and transference of certain traits, making it impossible to rule out or

⁶See *id.*, at 736.

⁷See Ron Gasbarro, *Combating Growing Bacterial Antibiotic Resistance*, AMERICAN DRUGGIST, Feb. 1996, at 49.

⁸See *id.*

⁹See Stuart B. Levy, *THE ANTIBIOTIC PARADOX: HOW MIRACLE DRUGS ARE DESTROYING THE MIRACLE* 6 (1992).

¹⁰See Misocky, *supra* note 5, at 735.

¹¹See Markow, *supra* note 4, at 531.

¹²See *id.*

properly calculate the potential for a “superbug”.

Modern technology and medical practice presents even more challenging problems in the area of antibiotic resistance, in particular in the areas of genetic engineering and the proliferation animal drug use. In the areas of genetically engineered foods and animal drugs a threat is feared because of the capability of the spread of resistance in a stealthy manner that could compromise the safety of the population without scientists having any indicators or notice. Quite simply, these areas are a looming threat because they are largely unregulated and not entirely understood. While scientists can ably predict that antibiotic use in human will lead to resistance, the consumption of genetically engineered foods or meat tainted with antibiotic resistant bacteria is much harder to monitor and unpredictable as to how it will affect and spread through humans.

Fortunately, the FDA is in a unique position to play a role in the safe development of the aforementioned areas. While it is not a plausible option for the FDA to simply approve new antibiotics to combat resistance because the rate of development is not sufficient to keep up with the rate of newly-created resistant strains,¹³ there are alternative methods for the FDA in fighting the battle against antibiotic resistance. This paper will analyze the problems the FDA confronts within the fields of genetic engineering and animal drugs as it relates to antibiotic resistance. Finally, this paper will also suggest general strategies the FDA can pursue to address the potential epidemic of widespread antibiotic

¹³See Denise Grady, *A Move to Limit Antibiotic Use in Animal Feed: Fewer Hardy Bacteria in People is U.S. Goal*, N.Y. Times, Mar. 3, 1999, at A1.

resistance.

Part I. Genetically Engineered Food.

A. An Overview

The ability to genetically engineer crops, livestock, and microorganisms holds out hope for better food production, distribution, and as a possible solution to worldwide nutrition problems. In the past few years the new genetic modification capabilities have gone from the lab to the marketplace, sparking concerns over the implications. Indeed, nearly 80 million acres of transgenic crops were planted worldwide last year, including 50% of the soybean acreage in the United States.¹⁴ Armed with the technological capability for genetic engineering, many fear scientists do not have the insight to foretell or predict the consequences of gene modification in living organisms.¹⁵ Indeed, this is essentially an insurmountable problem. No matter how much knowledge and detail about a parent organism is known, any new life form is so complex that its potential harms and risks can not be ascertained, despite detailed knowledge about the organisms' anatomy or lineage.¹⁶

For example, in genetically engineered herbicide resistant plants scientists anticipated little environmental risk since the plants were unlikely to develop the invasive properties of weeds.¹⁷ However, within three years scientists found the herbicide resistant traits had transferred to nearby weeds through ordinary

¹⁴James P. Lucier, *Freezing Out the Farmers*, INSIGHT ON THE NEWS, Nov. 15, 1999, at 10.

¹⁵*Transgenic Agriculture: Biosafety and International Trade*, 4 B.U. J. SCI. & TECH. L. 4 para. 18 (1998) (comments of Michael Baram).

¹⁶Note, *Regulating Genetically Engineered Microorganisms Under the Toxic Substances Control Act*, 24 HOFSTRA L. REV. 223, 227-28 (1995).

¹⁷See *Transgenic*, *supra* note 15, at n. 57.

cross-pollination.¹⁸ This simple example helps illustrate the delicate and unpredictable character of nature. Living organisms act in seemingly random and yet interdependent ways, and even when scientists know the exact traits of an organism or plant, they are often unable to predict the consequences of those traits on the plant itself or the surrounding area when the new species is introduced into the environment. It is even more harrowing when one considers that for many genetically engineered plants and foods the traits that might pose a danger to nature or mankind will not even be apparent to scientists.

While the above example demonstrates the general concern over the complexity involved when manipulating naturally occurring organisms, the more specific and central concerns over genetically engineered items are divided into three categories: economic risks, environmental risks, and human health and safety concerns.

First, economic issues arise because small farmers can be driven out of the market since genetically engineered foods will be designed to be cheaper and easier to produce on an economy of scale.¹⁹ Smaller farmers and those who fail to use genetically altered crops will also be threatened because the most common pesticides, such as bacillus thuringiensis (“Bt”), will be genetically built into plants, altering the environment with this sustained use of Bt so that alternative methods of farming will become obsolete due to the immunity pests will develop to many pesticides unless present at the abnormally high rates that

¹⁸See *id.*

¹⁹Kirsten S. Beaudoin, *On Tonight's Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 MARQ. L. REV. 237, 243 (1999).

will be found in genetically engineered crops.²⁰ Such a use of pesticides has been analogized to indiscriminate use of antibiotics since the pesticides are used without regard to need or infestation, while also threatening other life, such as the monarch butterfly in the example of Bt.²¹ The farming market will be under the control of the biotech companies, leaving farmers to either accept the terms of biotech companies or risk losing their business as those farmers using genetically altered crops drive everyone else out of the market. One company, Monsanto, has even gone so far as to splice a soybean seed with “Terminator Technology” so that the seed becomes sterile after a period of time, ensuring that the farmers must order seeds every year from the company.²² While one could argue a market system is better, when the threat is the monopolization of our food supply by a few companies, regulation is needed, less we risk the health and wallets of the public.

Environmental risks, the second category, relate to the discussion earlier in this section. Because living organisms always change, adapt, and replicate, it is an impossibility to determine the future consequences of genetic modification.²³ Introducing engineered plants and organisms into the food chain is inevitably unpredictable, regardless of how much scientific data is accumulated. One of the main environmental risks cited is that genetically engineered plants pose a significant threat to biodiversity once introduced into the food chain.²⁴

²⁰See *id.*, at 244.

²¹Jeannette Batz, *Why Missouri Botanical Garden's Peter Raven, World-Renowned Environmentalist, Courts Monsanto's Favor, Boosts Its Biotech and Takes Its Money*, RIVERFRONT TIMES, Nov. 3, 1999.

²²See Beaudoin, *supra* note 19, at 244.

²³See *id.*, at 245.

²⁴See *id.*

The third category, human health and safety, is obviously the most compelling. The type of problems here cover the spectrum. For example, on one end there is the possibility of the creation of irritants within everyday food. This occurred in the mid-1980s when a new strain of celery was produced that was highly resistant to insects.²⁵ Unfortunately, it was later discovered that when people handled the celery sticks they were developing severe skin rashes caused by the shedding of psoralens, natural chemicals which become irritants when exposed to sunlight.²⁶ On the other extreme rests the possibly fatal or severely damaging health effects. For an example of the extreme rhetoric and heated controversy these types of concerns can wreak, look at the debate over Posilac, or what is commonly called recombinant bovine somatotrophin (rBST) or bovine growth hormone (BGH).²⁷ The debate over BGH demonstrates science's inability to accurately evaluate genetically altered products and the potential for consumer hostility on an international scale. For example, because of the controversial claims that BGH has carcinogenic qualities, Canada has banned BGH, while the United States approves of the use of BGH to increase milk production in dairy cows.²⁸

Despite all of these problems associated with genetically engineered foods, perhaps the most feared threat is the possibility of antibiotic resistance. The next section will deal specifically with the threat of antibiotic resistance in humans as it relates to genetically engineered foods and plants.

²⁵Phil Cohen, *Living in a GM World*, NEW SCIENTIST, Oct. 31, 1998, at 42.

²⁶See *id.*

²⁷See Beaudoin, *supra* note 19, at 246.

²⁸See *id.*, at 248.

B. Antibiotic Resistance and Genetically Engineered Foods

Antibiotic resistance is a risk that occurs because of the inability to predict the results of genetic modification. If plants or foods contain bacterial genes that cause antibiotic resistance it could quickly enter the human population if those crops are consumed by humans, are feed for animals that are consumed by humans, or simply affect the ecological chain and corrupt plants or foods that fit into the above categories.

The reasons why scientists fear genetically engineered plants pose a threat deserves explanation. When plants are genetically modified by mixing proteins across species lines, some of the transferred proteins will come from bacterial genes, meaning that antibiotic resistance is a distinct possibility if the crop enters the human food chain.²⁹ Considering that genetic engineering will focus on those plants fit for human consumption, a very real risk is apparent. An additional risk resides, of course, in the increased use of antibiotics to fight infection because of engineered foods, which would be correlative with an increased use of antibiotics by people hoping to prevent possible infection as genetically engineered foods saturate the market.

However, the main risk of antibiotic resistance exists largely because of the process by which scientists handle DNA in the creation of genetically engineered plants. When identifying DNA in bacteria and plants, scientists use antibiotic

²⁹See *Transgenic*, *supra* note 15., at para. 23.

resistant genes as “markers”. There is a threat that these markers, even though genetically scrambled, could resurrect themselves and boost the spread of antibiotic resistance in humans.³⁰ These markers, used in genetically engineered foods to show genetic transformation, are believed by many commentators to pose a significant risk of spreading from plants to man.³¹

The FDA’s framework for approving and monitoring genetically engineered foods is loose and susceptible to flaws. The next section will discuss recommendations for helping to improve the safety of the public that will be consuming genetically engineered foods in increasing quantities over the next few years.

C. Recommendations for the FDA Concerning Genetically Engineered Foods

One of the first things that needs to be realized is the complete lack of a structural process for the approval of genetically modified foods by the FDA. Much like the GRAS exemptions for food additives, it is up to the discretion of the producer of the genetically engineered food to determine if further testing is required.³² As the FDA has said since taking a stance in 1992, “[The] FDA has not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants.”³³ Like letting the fox guard the hen house, letting biotech firms determine if lengthy testing and delays for entrance into the marketplace is required is setting up a system where the perverse incentives

³⁰See Cohen, *supra* note 25, at 42.

³¹*Health Risks of Genetically Modified Foods*, THE LANCET, May 29, 1999, at 1811.

³²*Seeds of Change*, CONSUMER REPORTS, September, 1999, at 41.

³³See *Health Risks*, *supra* note 31, at 1811.

will ultimately lead to poor decision-making. Indeed, companies only need to bring summaries of their studies to the FDA to gain access to the market, never allowing the FDA to see any real data.³⁴ Unlike GRAS exemptions for food additives, the regulatory scheme here makes little sense because there is no long term use or understanding of genetically engineered foods that can ensure the safety of the public. Recombinant DNA is a far cry from butter or salt, yet the FDA insists on applying the same regime to both cases.

Fully aware of the efficiency concerns at stake in testing of genetically engineered foods for pre-market approval, perhaps the best system is one where microcosm testing is performed. Microcosm testing simulates the environment the food or plant will be introduced to and provides a small-scale model for how the genetically engineered organism will react in nature.³⁵ Scientists can replicate nature by using plants, soil, and other organisms that will be present at the planned release site and simulate the climate and moisture present at that site.³⁶ Scientists can then gauge the likely result of putting the crop into nature, including measuring likely changes on the environment and on the plant itself. However, the FDA must ensure the process for testing and approving such crops is systematized, or else there is a risk of manipulation of the scientific processes. Considering the potentially devastating economic and safety issues that genetically engineered crops present, this process would provide at least a basic safeguard against the possible consequences of modified crops. After all, it is the

³⁴See *id.*

³⁵See *Transgenic*, *supra* note 15., at para. 43.

³⁶See *id.*, at para. 44

fear of the unknown changes that occur in nature that most spur the fears about genetically engineered foods causing an increase in human antibiotic resistance. If the interrelations of the environment are better understood, the possibility of antibiotic resistant traits in plants and the likelihood of crossover to humans can be calculated.

This process will incur expense, but it is an expense that should be directed at the biotech companies. These companies will have to engage in the required testing and present their full data to the FDA, but it is a system they will be willing to endure considering the potentially huge profits they would reap by increasing the quality and production of their products with genetically engineered products. Viewing the volatile environment surrounding the debate about the danger of genetically modified crops, such a systematic process for approval might also provide long-term stability for companies once they understand their products will be approved if they follow FDA guidelines. This, in turn, will encourage companies to pursue the necessary research. As it is now, biotech companies realize the uncertain environment and have every incentive to push through their products without adequate testing since they understand that the standard for approval could change at any time. Particularly in an area like antibiotic resistance a simple chemical analysis for toxicity will not suffice. The status quo, therefore, is hardly likely to adequately protect the public.

Review of the data will necessarily mean more resources spent by the FDA, but considering the high-profile nature of genetic engineering issues, it is likely that more resources can be granted to FDA by Congress. The public is extremely

concerned about genetic engineering, and such a touchy issue is likely to be seen by Congress as justifying further FDA expenditures of time, money, and people. Less resources will be required in this area as time goes on since certain genetically engineered products, much like in the area of food additives, will become accepted as safe, and biotech companies will no longer have to go through the same procedures, instead relying on a GRAS-like exemption.

A second solution for the FDA is to label genetically engineered products. This is keeping directly in line with the purpose of the FDA to protect and inform the public so individuals can have a legitimate consumer choice. This is particularly appealing here, where all sides are divided as to the actual danger posed by genetically altered products.

The specifics of the scheme could be ironed out, but one suggestion which could avoid any Constitutional speech problems would be a voluntary labeling idea for companies to market foods that were not genetically engineered.³⁷ This “positive” scheme avoids the problem of forcing producers to engage in what might be labeled as speech when the government mandated labeling of genetically engineered products. Of course, the biotech companies will complain that this scheme will imply an inferiority of their products since the non-genetically engineered label will serve essentially as a stamp of approval, but at least the choice will be in the consumer’s hands, and not a choice unlike decisions now based on nutrition labeling. It still is important to note that a scheme forcing biotech companies to label their products would probably be held constitutional since

³⁷See Beaudoin, *supra* note 19, at 253.

providing consumers with health information encompasses such a compelling interest on behalf of the government.

Labeling is an appealing solution because of the current information available to the public, mainly meaning little or none. In a survey done by the International Food Information Council 71% of American viewed themselves as poorly informed about genetically engineered foods.³⁸ In an area where there is legitimate debate that is often layered with misinformation because of vested interests, perhaps public awareness is the needed catalyst for the proper research on the dangers of genetically modified foods to take place. In addition, if the research is inconclusive at least the government will have an accurate representation of how the public weighs the benefits versus the risks by which products are purchased. Perhaps in appraising the issue, the public opinion should weigh heavily in the government's final approach to the problem. After all, it is not as if the government has been able to come to a consensus on the issue. In other words, a labeling scheme might be the best way to approach risk-assessment.

Along the same lines, public opinion about the FDA might be bolstered if labeling for genetically engineered products was included. A labeling scheme would show the FDA is trying to play an active role in guarding the public in the fast-paced world of modern food technology. The public already shows a desire to know the process by which a product was made; just look at the booming organic food industry as evidence that people are avoiding the uncertain modern industrial processes. It would be hard to deny that people are at least pay-

³⁸See *Seeds*, *supra* note 32, at 41.

ing more attention to the methods that produce their foods. For example, one recent poll by *Time* magazine showed the public supported the labeling of genetically engineered foods by an overwhelming 81 %.³⁹ At the very least, labeling will ensure the public is aware of the amount of genetically engineered products they consume, and because of this awareness there will be an avoidance of diets overly concentrated with these foods. This overconcentration is important since it could take large quantities of a specific altered food to increase the risk of antibiotic resistance to a statistically significant level. If there is a decrease in use, or at least the avoidance of a diet dominated by one particular genetically altered food, there is a decreased chance that antibiotic resistance will occur. A labeling scheme also prevents the essential blackmailing of the FDA by biotech companies with threatened lawsuits. As one scholar said, “the lack of federal guidance permits a mounting litigious battle.”⁴⁰ Genetically altered food product manufacturers have taken a litigious strategy already to manipulate the FDA into discarding the labeling idea.⁴¹ By going ahead and implementing the labeling structure, this threat by the biotech industry is ameliorated, and any short-term lawsuit wave will be outweighed by the long-term lack of lawsuits and threats to try and preserve the status quo.

Labeling might also be a good economic idea when one considers the international view of genetically engineered foods. Internationally biotech companies are viewed with far more skepticism, and much of it is driven by a grassroots

³⁹See *id.*

⁴⁰See Beaudoin, *supra* note 19, at 239.

⁴¹See *id.*, at 249.

movement against genetic engineering.⁴² The movement has achieved a large amount of success, and recently the European Union announced a moratorium on new approvals of genetically engineered foods until better EU safety regulations are put into place in 2002.⁴³ If the US was to institute labeling for genetically modified food products this might facilitate more trade with the international community. Under the labeling system countries could know which foods were genetically altered and the label might serve to generate a feeling of security around genetically engineered products. Forthright labeling implies honesty and safety, and this security would make foreign powers more willing to deal with the US food market. Feeling of subterfuge and mistrust, even subtly implied, could be disastrous in international trade negotiations.

Instituting further regulations is necessary to prevent the potentially disastrous harm of widespread antibiotic resistance through genetically engineered foods. Both microcosm testing and labeling would, for the reasons discussed, implement safeguards against potential harm by generating additional awareness about the potential consequences of genetically engineered foods and, hopefully in turn, produce increased knowledge.

⁴²Ronnie Cummins and Ben Lilliston, *The Rise and Fall of "Franken-Food"*, EARTH ISLAND JOURNAL, Dec. 22, 1999, at 30.

⁴³See *id.*

Part II. Animal Drugs and Antibiotic Resistance.

A.

An Overview

Drugs, specifically antibiotics, are administered to animals routinely to treat sickness, prevent illness, and promote the growth of animals.⁴⁴ Indeed, 40% of all antibiotics used in the U.S. are fed to animals being raised for their food potential.⁴⁵ The only use that many feel should be permitted is the therapeutic use of helping sick animals. It is the sub-therapeutic uses, i.e. when the animals are not sick, that causes scientists to be concerned. The most common way to administer the antibiotics is through animal feed.

The use of antibiotics is essential in modern farming. Without sub-therapeutic doses of antibiotics modern factory farming, which concentrates large number of animals in a small amount of space, would not be possible.⁴⁶ Animals can only survive the disease and health problems that naturally accompany close confinement if they receive antibiotics.⁴⁷ In addition, subtherapeutic doses of antibiotics promotes growth, which means larger animals, more eggs from chickens, and more milk from cattle.⁴⁸ In addition, antibiotics are often sprayed in subtherapeutic doses on fruit to prevent disease.⁴⁹ A subtherapeutic dose is

⁴⁴Linda Weinberg, *How Overuse of Antibiotics on Farms Threatens Your Health: What to Do*, ENVIRONMENTAL NUTRITION, Nov. 1, 1999, at 1.

⁴⁵See id.

⁴⁶Barbara O'Brien, *Animal Welfare Reform and the Magic Bullet: The Use and Abuse of Subtherapeutic Doses of Antibiotics in Livestock*, 67 U.COL.L.REV. 407, 413 (1996).

⁴⁷See id., at 412.

⁴⁸See id., at n.24.

⁴⁹See Weinberg, *supra* note 44, at 1.

typically one to ten percent of a therapeutic dose to treat a sick animal.⁵⁰ In other words, the agricultural industry is wholly dependent on the widespread use of antibiotics to produce at its current rate. In turn, the industry keeps the grocery shelves full while keeping consumer cost down. However, there is controversy surrounding the industry's current practice, and the concern extends far beyond just the outrage over the conditions that many animals live with modern farming.

B. Antibiotic Resistance and Animal Drugs

The debate over animal drugs and antibiotic

Resistance in humans is nothing new. Indeed, since the early 1970s the FDA has focused on the issue every 5-10 years, though never coming to a consensus as to what approach to take.⁵¹ The basic fear is that antimicrobials in livestock will trigger a resistant bacteria that could infect humans, whether through direct exposure or by eating meat with the resistant bacteria.

As an example of the FDA's concern over animal drugs is the newly proposed framework for evaluating new animal drugs in food-producing animals.⁵² Essentially, the new framework would classify new and existing antibiotics based upon their importance to human medicine, set thresholds based upon acceptable levels of susceptibility of pathogens to antibiotics, and then monitor this

⁵⁰See *id.*

⁵¹See Karen McMahon, *Putting Animals at Risk*, FARM INDUSTRY NEWS, Apr. 1999, at 1.

⁵²See generally Wes Ishmael, *Hazard v. Risk*, ACCESS CONTROL & SECURITY SYSTEMS INTEGRATION, May 1999.

susceptibility to ensure safety in the future.⁵³ Many have criticized these regulations as too restrictive since most antibiotics used in veterinary medicine are common to those used in human medicine, though there are rare exceptions such as ionophores.⁵⁴

Despite this new regulation, there is still considerable debate over whether antibiotics used with animals are a threat to humans. For example, there is no directly documented case where antibiotic use in animals has caused treatment failure in humans.⁵⁵ However, studies are showing a link. For example, a group of Minnesota health specialists reported in the *New England Journal of Medicine* that the approval and use of a drug in chickens was followed by an eightfold increase in drug-resistant food poisoning involving the same drug.⁵⁶ The particularly disconcerting fact is that the drug in question was quinolone, a drug of first resort for doctors.⁵⁷

With the evidence on both sides still contested, there is debate on exactly how antibiotic resistance would spill over into the human population. For example, there is the potential for antibiotic resistant food poisoning from eating meat with resistant bacteria, leading to dangerous cases of listeria, *E. coli*, salmonella, and campylobacter.⁵⁸ It is eating these foods with resistant bacteria that poses the real threat, not from eating food laced with traces of antibiotics. Additionally, farmers and workers in slaughterhouses can become exposed to the

⁵³See id.

⁵⁴See id.

⁵⁵See id.

⁵⁶See Dick Thompson, *Drugged Chicks Hatch a Menace*, *TIME*, May 31, 1999, at 81.

⁵⁷See id.

⁵⁸See Audra Hingley, *Campylobacter: Low-Profile Bug is Food Poisoning*, *FDA CONSUMER*, Sept. 1, 1999, at 14.

dangerous resistant bacteria just through contact with the animals.⁵⁹ Without proper cleaning, ingestion of bacteria can inadvertently occur. Crops also retain the bacteria in question if they are fertilized with the manure of animals given antibiotics.⁶⁰

The stakes are high, but the evidence is confusing and sometimes conflicting. However, considering the risk involved with antibiotic resistance there should be appropriate precautions taken by the FDA.

C.

Recommendations for the FDA Concerning Animal Drugs

The FDA, as could be expected with its limited resources, is only able to focus so many hours on animal drugs. Since the link between animal drugs and human illness is so tenuous, the FDA perhaps wisely has avoided allocating too many resources into this area. However, considering the recent evidence on the subject and the devastating possible risk (even if proven statistically small), the FDA should institute better safeguards in the area of animal drugs.

The first step the FDA needs to take is a better monitoring procedure for the distribution of animal drugs.⁶¹ While it might not be realistic to expect a company like Monsanto to report possible flaws in their products, the threat of possible criminal charges might have the necessary inducement. This could

⁵⁹See O'Brien, *supra* note 46, at 426.

⁶⁰See *id.*

⁶¹See cf. David Abouafia, *Pushing RBST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin to America*, 15 PACE ENVTL. L. REV. 604, 644 (1998).

be done through manufacturers, veterinarians, and feed producers. If a central form can be produced and sent in by the above groups, and the processing done perhaps jointly with the USDA and EPA, the FDA would understand the usage, amount of doses, and could also monitor adverse reactions within animals. Such a system might also allow better checking of possible human resistance through animal drugs, or at least an earlier indication of possible spill over into the human population. Plus, if there is a system of monitoring in place it should make the distributors and users of antibiotics more aware and cautious in the amount they use and the drugs they put into the market. Just by having the system in place it should serve to edify people that the FDA considers antibiotic resistance a real health threat to the nation.

Additional testing of animal drugs is perhaps also needed. Expense is a concern here, but the addition of user fees for animal drugs could perhaps offset the cost. That seems like a small price to pay considering the risk at stake. Political feasibility would be an issue, but the hot issue of antibiotic resistance could help offset the political vulnerability of the user fee idea. The same idea discussed with genetically engineered food, microcosm testing, could apply here. Perhaps new animal drugs, specifically antibiotics, could be tested on the main food-producing animals. The animals could be tested for resistance, and any products derived from those animals could be tested for a build-up of resistant bacteria. Giving the food products to test animals might also help to demonstrate the possible effects of consumption of the products. Clearly, this would not be a perfect system since the duration and quantity of use could not be sim-

ulated. However, truly dangerous products might exhibit resistance in a short amount of time. Perhaps even more importantly, companies will realize these tests will be performed and therefore will be more cautious in the design of new animal drugs.

The cost of the testing will be shouldered by the companies. The cost will be miniscule in comparison to the potential profit, but this regulation might be viewed more favorably for other reasons. For one, it is an assurance that the animal drugs will not be banned or severely restricted. Second, it will enhance the industry's image within the public eye. Finally, the regulations can help foster a cooperative spirit between industry and the FDA since the findings of the FDA will be based upon the research of the companies, and will not just be a regulatory hand swooping down for unknown and arbitrary reasons.

The final solution suggestion, and the one that should provide immediate benefit, is an educational campaign to notify people of the risks of food poisoning. A simple campaign to let people know that washing their knives, cutting boards and hands after handling food could reduce possible risks without riling up industry.⁶² While this knowledge might be common place, a reinforcement of its usefulness would help, plus an announcement that additional risk now existed because of animal drugs might serve to motivate more people to take the correct precautions with their food.

A final topic should be addressed on animal drugs. Many have suggested that the only safe route to take is to completely ban antibiotics from use in animals,

⁶²See Thompson, *supra* note 56, at 1.

in particular the use of antibiotics in animals feed. At the very least, people think that a few antibiotics should be banned, such as penicillin and fluoroquinolones, because of their widespread human use.⁶³ However, this seems like an overreaction to the problem. For one, there is a concrete benefit to using antibiotics in overall growth of animals and increased food production. Compare this to the highly debated risk of widespread human antibiotic resistance because of these animal drugs.⁶⁴ The FDA, a known conservative agency, would certainly consider such a ban if there was truly a substantiated link between animal drugs and the possibility of large-scale human illness. Until that link is agreed upon by scientists, forcing farmers to quit using animal drugs would severely restrict farmer's incomes, increase food prices, and cause chaos in the agricultural and food markets.⁶⁵ Besides, the cost of enforcing the ban on any or all antibiotics would be astronomically high in terms of money and manpower. In other words, a ban would be a pragmatic impossibility because of the available FDA resources.

The FDA's current proposal, by subjecting certain antibiotics considered necessary for human use to more stringent scrutiny, enables the use of helpful antibiotics while still ensuring that problems with particular antibiotics are caught early and dealt with swiftly. The suggestions in this paper would additionally further the goal of watching the public safety while not overreacting and cre-

⁶³Patricia B. Lieberman, *Control Antibiotic Use*, THE NEW YORK TIMES, Nov 7, 1999, at Sec. 4, 14.

⁶⁴See *Human Health Risks with the Subtherapeutic Use of Penicillin or Tetracycline in Animal Feed*, INSTITUTE OF MEDICINE REVIEW (1989), at 7.

⁶⁵See *Antibiotic and Sulfonamide Drugs in the Feed of Animals*, 38 FED. REGISTER 9811 (Apr. 20, 1973).

ating panic and turmoil. The high stakes mandate a careful approach, but the uncertainty also requires a practical one.

In conclusion, antibiotic resistance is such a threat because of the possibility of it harming the human population without much notice, perhaps leaving scientists unable to determine the cause of human illness or increased antibiotic resistance. The measures mentioned in this paper all serve to help provide the FDA with the ability to closely monitor animal drugs because of their threat, yet these measures do not compromise farmer's livings or the current agricultural market by overreacting to an unknown and unverified threat. This seems to be in direct alignment with the FDA's purpose of formulating policies that best protect and enrich the lives of American citizens.

Part III. Recommendations for Dealing with the General Problem of Antibiotic Resistance

Antibiotic resistance is a problem that has plagued the FDA for many years, perhaps because of its inevitability. Antibiotics are invaluable to medical science, but the use of antibiotics necessarily creates strains of resistant bacteria. While genetically engineered foods and the use of animal drugs creates potentially pandemic problems of antibiotic resistance, the major problem currently is simply overuse and overprescription of antibiotics.⁶⁶ Doctors improperly prescribe antibiotics as a panacea drug on a routine basis. For example, antibiotics are often prescribed for upper respiratory infections (i.e. the common cold) and middle ear infections, yet these are viral infections that antibiotics are useless against.⁶⁷ It is this direct problem of misuse that the FDA can attack far more easily and perhaps effectively.

The first suggestion to deal with the overuse of antibiotics by people is to institute a distribution limit. This could be done by requiring physicians run a check for bacterial infection before pharmacies are allowed to distribute antibiotics. This requirement could easily be fulfilled electronically with communication between the pharmacy and the manufacturer of the antibiotics, and would ensure that doctors were prescribing antibiotics for bacterial infections, and not the common cold.⁶⁸ Such a system would serve to educate some doctors, while simply reminding other doctors of the proper use of antibiotics. This simple

⁶⁶See generally Sandra Levy, *Nader Urges Stricter Oversight of DTC Advertising of RX Drugs*, DRUG TOPICS, Mar. 15, 1999, at 16.

⁶⁷See Markow, *supra* note 4, at 531.

⁶⁸See Margaret Gilhooley, *When Drugs are Safe for Some But Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927, 946-47 (1999).

distribution limitation would cut to the heart of the antibiotic resistance problem, without having to create a complex regulatory scheme or adding additional layers to new antibiotic approval. Considering the inevitability of antibiotic resistance, still allowing antibiotics to be approved in the same manner as the status quo is important. New antibiotics will be a simple solution to antibiotic resistance, and this distributional limit will only indirectly and minimally effect incentives to invest in new antibiotic development. The market will still remain huge for antibiotics so the profit potential is not destroyed, and any loss of incentives to create new antibiotics is more than outweighed by the good health and preventative measures having a distributional limit would impose. At the very least, physical examination should be required before antibiotics can be prescribed by a physician.⁶⁹ Of course, narrow exceptions can be tailored when physical examination is impossible. Having the American Medical Association's involvement could be critical, not only for public relations but for the ability of the AMA to provide teeth to this proposal by threatening penalties against doctors that fail to properly prescribe antibiotics.

The second suggestion for curbing the overuse of antibiotics is the classification and restriction of certain antibiotics, specifically within hospital pharmacies. Those antibiotics classified as restricted could only be approved for use after consultation with the infectious disease department of the hospital.⁷⁰ Restricted antibiotics will be those the medical community views as essential to protect, specifically those antibiotics that have been successful without a demonstration

⁶⁹See Misocky, *supra* note 5, at 756.

⁷⁰See Markow, *supra* note 4, at 531.

of resistance within the human population. This additional distributional limitation could function in conjunction with the first suggestion, ensuring that doctors consider the importance of their prescription and then additionally are restricted in the type of antibiotics they can prescribe. Antibiotic misuse will be curbed, and specifically the misuse of essential antibiotics will be minimized. One would hope that a program like this could be done voluntarily by hospitals with any needed assistance provided by the FDA. A voluntary program would preserve the resources of the FDA, and can also be just as effective as a governmental program, evidenced by the current voluntary program at Mount Sinai Hospital.⁷¹ Indeed, the program at Mount Sinai goes even further than this proposal by also requiring constant education of physicians on antibiotics and conducting surveillance, analysis, and monthly reports on the use of antibiotics within the hospital.⁷²

Finally, the last suggestion would be required additional labeling warnings on certain antibiotics by the FDA. A warning label on certain antibiotics concerning appropriate use and dosage would serve as an additional layer of protection against improper prescription by physicians and to provide the patient with an understanding of the risks of taking antibiotics.⁷³ Considering the current problem of overprescription and improper prescribing by physicians, such labeling seems essential to provide consumers with enough information so that they can know whether they wish to follow their doctor's advice. Labeling might also

⁷¹See *id.*

⁷²See *id.*; For a discussion of another voluntary distributional limiting program that worked involving thalidomide see also Gilhooley, *supra* note 68, at 943-44.

⁷³See *id.*, at 948.

serve as a deterrent effect for manufactures and physicians by exposing them to more tort liability if there are misuses of antibiotics. Knowing this, physicians and manufacturers will be sure that antibiotics are used in a more responsible way.

The threat feared posed by genetically engineered foods and animal drug use is apocalyptic but unknown, but the immediate and definite threat of antibiotic misuse can be countered with the above suggestions. The key is alerting physicians to the problem, and forcing them to be aware and responsible for their role in the problem. With cooperative efforts between doctors and the FDA, education about the problem of antibiotic resistance will reach physicians and patients alike, and that will go a considerable way towards solving the problem.

Conclusion

Antibiotic resistance is one the more perplexing problems the FDA has encountered. However, the FDA is in a unique position to play a positive role.

For one, the FDA has expertise and statutory authority over drugs. The FDA is the agency that people will expect to deal with a problem involving antibiotics precisely because of their expertise and authority. Second, the FDA is unique among agencies because it has public respect and confidence. The FDA, more than any other agency, can bring physicians, manufacturers, and scientists to the negotiating table to reach solutions to this complex problem. This ability to bring groups together will be critical in the area of antibiotic resistance where there is such controversy.

Antibiotic resistance poses a threat to mankind. Whether the threat is indirect and debated, such as the harm feared because of genetically engineered food or animal drugs, or more direct and verifiable, such as the misuse of antibiotics by people, the FDA can play a central role in curbing the threat. The key is to act swiftly, before the potential harm is realized.