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HEARING ON ``ANTIBIOTIC RESISTANCE AND THE USE OF ANTIBIOTICS IN ANIMAL AGRICULTURE''

WEDNESDAY, JULY 14, 2010

House of Representatives,

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 2:12 p.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [Chairman of the Subcommittee] presiding.

Members present: Representatives Pallone, Dingell, Schakowsky, Baldwin, Barrow, Christensen, Murphy of Connecticut, Space, Braley, Waxman (ex officio), Shimkus, Buyer, Pitts, Sullivan, Murphy of Pennsylvania, Blackburn and Gingrey.

Staff present: Ruth Katz, Chief Public Health Counsel;

Sarah Despres, Counsel; Rachel Sher, Counsel; Stephen Cha, Professional Staff Member; Emily Gibbons, Professional Staff Member; Virgil Miler, Professional Staff Member; Alvin Banks, Special Assistant; Allison Corr, Special Assistant; Eric Flamm, FDA Detailee; Karen Lightfoot, Communications Director, Senior Policy Advisor; Elizabeth Letter, Special Assistant; Lindsay Vidal, Special Assistant; Mitchell Smiley, Special Assistant; Clay Alspach, Minority Counsel, Health; and Ryan Long, Minority Chief Counsel, Health.

Mr. {Pallone.} The meeting of the Health Subcommittee is called to order, and the subcommittee is convening today for its third hearing to discuss antibiotic resistance and its threat to public health. Today we will examine the use of antibiotics in food-producing animals and the impact of this use on human health.

Antibiotics, as you all know, are among the most significant medical innovations of the 20th century. The CDC lists control over infectious disease as one of its top 10 great public health achievements of the last century, and antimicrobials are crucial to that accomplishment. And yet we must collectively be alarmed that we are undermining the power of antibiotics by failing to use them judiciously. In past hearings, we have heard testimony about physicians that are prescribed antibiotics just in case their patients have bacterial infections, and we all know patients that have stopped taking their antibiotics once they felt better, even if they didn't finish the treatment. It is clear that the consequences of such actions are severe. Manmade antimicrobial resistance weakens our options to treat pneumonia, food-related diseases including E. coli and Salmonella, and hospital-acquired infections, commonly known as MRSA.

Our examination of antibiotic resistance would not be complete without a discussion of the use of antimicrobials in animals. It is very timely that we are having this hearing today. Last month the FDA issued draft guidance detailing its position that using medically important antimicrobial drugs for food production purposes threatens the protection and promotion of the public health. FDA will state today that antibiotics should only be given to animals under supervision of a veterinarian and should only be used to assure animal health and not to promote growth. We will have the opportunity today to hear from the major experts and stakeholders in the field about reactions to FDA'S draft guidance and the overall debate on how animal use of antibiotics impacts human health.

As we consider future action to limit antibiotic resistance, it would be helpful to hear about the Danish experience. Starting in 1995, the Danish government implemented aggressive steps to limit the use of antibiotics in food-producing animals and collected extensive data that they and the World Health Organization used to evaluate the effects of these actions. Clearly, any future action to limit antibiotic resistance must be carefully considered and guided by science.

We have two great panels today of government and private

witnesses with 10 people total testifying who will contribute to this discussion, and I know that many of the witnesses rearranged their schedules today to be here including Dr. Josh Sharfstein at the FDA. We greatly appreciate your ability. However, I am going to have to say one thing you are not going to like, and that is that unfortunately as too many times has been the case here, we did not get the testimony within 48 hours before the hearing. I know that the hearing was changed, I guess, from tomorrow to today but we notified everybody 3 weeks ago of that, and the FDA testimony arrived at about 6 p.m. Tuesday, which was last night, and the CDC testimony also arrived late in the day on Tuesday, which obviously doesn't make the 48 hours, so please in the future, it is really important that we get the testimony 48 hours before the hearing. Otherwise we really can't adequately prepare for the hearing, so I just want to mention that, and I don't want to be difficult but it really is important.

[The prepared statement of Mr. Pallone follows:]

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Mr. {Pallone.} With that, I will yield to our ranking member, the gentleman from Illinois, Mr. Shimkus.

Mr. {Shimkus.} Thank you, Mr. Chairman, and thank you for obviously the admonition about getting testimony in, and I appreciate that. I know is not easy.

Thank you all for coming. The debate centers around whether antibiotic use in animals presents a safety risk for humans. Rather than focus on theory, we must really rely on the science behind the issue. So far there is nothing that links use in animals to a build-up of human resistance, and so I will be focusing on, I know it sounds crazy, but real science, real peer-reviewed science and testing, which in previous testimony, and I have the record from the previous hearings that we have done none in this country. There has been no testing in this country on this connection. So the challenge will be to not move in public policy until we verifiable peer-reviewed science to address this issue.

We do know through the hearings that people are overusing and misusing antibiotics and that leads to faster development of resistance of drugs in the body, and when it comes to people getting sick from foodborne antibiotic-resistant strains, evidence shows it is again from humans through handling food, not animals. Even then because of our

rigorous oversight, foodborne illnesses in the United States have continued to decline over the past decade. Nevertheless, as science develops and we learn more, we can always work to improve risk-based approach to making people and the foot they eat safer. We should explore ways to strengthen our hazardous analysis and critical control points, plans across the spectrum from farm to fork.

At the same time, FDA should continue its strict approval path of antibiotics for animal use. The FDA process is resulting in increasing amounts of approved antibiotics that are not used in human medicine at all. As a result, those classes of antibiotics have no potential impact on human resistance while yielding benefits on the farm. Still, there are some who would ban use of antibiotics in animals similar to what occurred in Denmark in the late 1990s, and I know the chairman mentioned that, and I will be talking about that research too. Since the ban, Danish animals' death and diseases have increased. To control these increases, therapeutic use of antibiotics to treat sick animals more than doubled to a level greater than all antibiotic use combined prior to the year of the ban. So they banned it and we use more. Animals are not healthier; they are sicker. So that is why we do appreciate this hearing, and this question, we did make humans safer? No. Only did humans not become

any less resistant, they became more resistant to antibiotics in Denmark. Resistance increased in Salmonella, penicillin, tetracycline. At the same time those resistances in the United States have decreased to about half the level of Denmark. Before we go down a path that will have a devastating economic impact on our agriculture industry, we must ensure science drives this debate.

So again, I want to thank you, Mr. Chairman, for holding this hearing.

The last thing I do want to mention is that we have 10 witnesses today. This is our third or fourth hearing on antibiotics. We have not had a single hearing on the new health care law passed. We have asked for the CMS actuary. We have asked for Secretary Sebelius. Now we have a recess appointment, Dr. Berwick, who we like to see, who said some interesting things about rationing care and that we would do it with our eyes open, but I guess what is as telling as anything else why we need to have a hearing is, it seems that in the $160 million that we provided to Pennsylvania for the high-risk pool, abortion and abortion services are being expanded at taxpayers' expense. I thought this was a promise made to the pro-life Democrats in voting for the bill through the Executive Order. Obviously that was not the case and that is why we should have a hearing, and I yield back my

time.

[The prepared statement of Mr. Shimkus follows:]

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Mr. {Pallone.} Thank you, Mr. Shimkus.

The chairman of our full committee, the gentleman from California, Mr. Waxman.

The {Chairman.} Thank you very much, Mr. Chairman. I am pleased you are holding this third of a series of hearings on antibiotic resistance. This is a serious public health problem.

Our first hearing provided the context for understanding the nature of the problem, the scope, the statistics and the science that make up this emerging public health crisis. The focus of today's hearing, the use of antibiotics in animals, is an issue that has been raised by numerous members of this subcommittee as well many of our previous witnesses, representing both the public and private sectors, and I think we would all agree that the topic is complicated and controversial.

I believe we would also all agree on this point: By definition, antibiotic resistance is bred by the very use of antibiotics, be it by humans or by animals. To remain effective, then, antibiotics need to be used judiciously.

As we learned at our last hearing, antibiotics are being overprescribed in humans. That is a very real and difficult problem and one that requires our full and immediate

attention.

But the issue with animals is something else. For animals, we use antibiotics for purposes other than treating illnesses in the animal. As we will hear today, animals raised for food production are routinely provided antibiotics to prevent infections. In stark contrast to animals, we would be shocked if a pediatrician ever ordered antibiotics for an entire nursery school class to keep the children from being infected with strep throat. But in this country, that is standard practice for a barnyard full of pigs or cows or chickens. In addition, animals regularly are fed these drugs not to treat any illness at all but simply to promote growth. In both situations, this is an overprescribing of a very different sort.

There appears to be universal agreement on yet another point: The key to reducing antibiotic resistance is to reduce the use of antibiotics. The Food and Drug Administration recently announced one approach for achieving this goal with respect to animals. In June, the agency issued draft guidance which recommends that antibiotics not be given to animals to promote growth and that when these drugs are used, they should be administered only under the supervision of a veterinarian. This sounds to me like a very good first step.

But we must do more to tackle this piece of the antibiotic resistance puzzle and we must do so as part of a comprehensive strategy designed to safeguard the vitally important public health tool that is our antibiotics. I would like to put into the record a letter from Dr. Frieden, the director of the Centers for Disease Control to Chairman Pallone, and according to Dr. Frieden, ``The Centers for Disease Control and Prevention finds there is a compelling body of evidence to demonstrate this link between antibiotic use in animals and the resistance from the antibiotics.''

[The information follows:]

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Mr. {Pallone.} Without objection, so ordered.

The {Chairman.} It is critical we encourage the development of new drugs. It also essential to preserve the antibiotics we already have. That means we must move expeditiously to slow the advancement of antibiotic resistance in both humans and animals. In each instance, our strategy must be based on science. I agree with that statement. But science, not just the science that may fit our constituency but real science and the scientific evidence is now strong enough to create a consensus among major public health groups and experts around the world that the time has come to reduce the use of antibiotics in animals. Organizations as diverse as the American Medical Association, the Institute of Medicine, the World Health Organization, and as we will hear from both CDC and the FDA, they all agree: We must take action now.

This brings us to today's hearing. It is an important hearing. Mr. Chairman, I want to thank Dr. Sharfstein. He has been very accommodating to be here today. He accommodated us by rearranging his schedule. I happen to know that by watching television he has been very busy. I didn't see him out in Los Angeles at any of the beaches, so I think he has been working pretty hard and I have noticed he

has been involved in Avandia. We would like those statements in earlier, but I think they ought to cut you a little slack. At least I am going to make that comment. And the same is true for others but we do need these statements as early as possible.

I thank all the witnesses who are here. I particularly thank you, Mr. Chairman, for this hearing. I think this is going to be an interesting one. Let us follow the science. Thank you. Yield back.

[The prepared statement of Mr. Waxman follows:]

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The {Chairman.} Can I ask, Mr. Chairman, two statements by unanimous consent be added to the record, one from two California-based groups, the San Francisco Medical Society and Physicians for Social Responsibility in L.A. regarding the use of antibiotics for animals?

Mr. {Pallone.} Mr. Chairman, the--

The {Chairman.} I ask unanimous consent their statements be added to the record.

Mr. {Pallone.} The Republicans just want to look at it.

The {Chairman.} I certainly want them to look at it. Whether they agree with the statements or not, I think that the groups--

Mr. {Shimkus.} Reserving the right to object. We don't want to get into--

The {Chairman.} I will pull back and have you look at it, and then we will ask unanimous consent at a later time.

Mr. {Shimkus.} Thank you, Mr. Chairman.

Mr. {Pallone.} Okay. So we are going to proceed without at this point. I don't know, you took me back when you talked about seeing him on the beaches. I didn't realize you traveled from beach to beach.

The {Chairman.} I was in L.A. My district has a lot of beaches and I didn't see him at any of them.

Mr. {Pallone.} Next is the gentleman from Indiana. Oh you want to reserve your time. Okay.

[The prepared statement of Mr. Buyer follows:]

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Mr. {Pallone.} Then we go to the gentleman from Pennsylvania, Mr. Pitts.

Mr. {Pitts.} Thank you, Mr. Chairman.

This is now the third hearing this subcommittee has held on antibiotic resistance. First was on April 28th of this year and second was held on June 9th. There is no doubt that over the last 50 years antibiotics have saved countless lives worldwide. There is also no doubt that we are experiencing a growing amount of bacterial resistance to antibiotics, and many infectious diseases are becoming increasingly difficult to treat as a result.

For the purposes of this hearing, however, the key question is this: Does the use of antibiotics in feed-producing animals cause antibiotic resistance in humans? An exchange between Chairman Emeritus Dingell and Dr. Thomas Frieden, director of the Centers for Disease Control and Prevention, during the April 28th subcommittee hearing is instructive, and I will briefly quote. Mr. Dingell asked, ``There appears to be much debate over whether the practice of adding antibiotics to agricultural feed is thought to promote drug resistance. What does current science and surveillance tell us on this point?'' Dr. Frieden answered, ``I am not aware of evidence in this country that has

documented the spread from animals to humans, feed animals to humans.'' Mr. Dingell then replied, ``I am getting the impression from what you are telling us here is that we really don't know what the nexus between the feed with antibiotics is and when there is a point of danger and what is the level of danger and what research is going on.'' Mr. Dingell was right. There is much that we don't know about how the use of antibiotics in animals causes or does not cause antibiotic resistance in humans.

Clearly, more study must be done. However, until we have definitive scientific evidence, it seems to me that legislation like H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act, or PAMTA, as they are calling it, which seeks to eliminate the use of antibiotics in animals except for treatment purposes, is premature and potentially dangerous. I am pleased that it appears that the FDA is working with the scientific and medical community in its new guidance, and I am interested to see what the commend period produces. As I have said before, we should study and explore every possible cause of antibiotic resistance but we should let the scientific evidence guide us.

I look forward to hearing from our distinguished panel of witnesses today. Thank you, Mr. Chairman. I yield back.

[The prepared statement of Mr. Pitts follows:]

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Mr. {Pallone.} Thank you.

The gentlewoman from Illinois, Ms. Schakowsky.

Ms. {Schakowsky.} Thank you, Mr. Chairman, for your leadership on this issue.

The CDC has described antibiotic resistance as one of the world's most pressing health problems and overwhelming data proves that antibiotic resistance is increasing in this country. This is a safety issue, a public health issue and quite frankly an issue of national security.

Mr. Chairman, I would like to submit for the record statements regarding the need for legislative action to protect the effectiveness of antibiotics, legislation like the Preservation of Antibiotics for Medical Treatment Act. These letters are from organizations including the American Medical Association, the American Academy of Pediatrics, Consumers Union, Union of Concerned Scientists, and over 1,000 individual physicians from across the country who have concluded that the non-judicious use of antibiotics in livestock is a problem of public health. So if I could submit these for the record?

Mr. {Shimkus.} Reserving the right to object, Mr. Chairman, just so we get a chance to look at them.

Ms. {Schakowsky.} On June 28th, the FDA released draft

guidance on this issue. The report states that ``The overall weight of evidence supports the conclusion that using medically important antimicrobial drugs for production or growth-enhancing purposes in food-producing animals is not in the interests of protecting and promoting the public health.'' In other words, pumping animals full of non-medically necessary antibiotics is not good for public safety. I want to point out that this guidance carries no enforcement mechanism but rather asks the industry to voluntarily follow these suggestions.

It is obvious to me that legislation is needed. Eighty percent of the meet randomly tested by the National Antimicrobial Resistance Monitoring System shows traces of antibiotic-resistant bacteria. Antibiotic resistance is not a victimless phenomenon. Seventy percent of the 98,000 people a year who die from hospital-related infections had a microbe resistance to one or more antibiotics.

Mr. Chairman, I have looked forward to this hearing for quite some time because it provides an opportunity to get the facts straight. I want to leave today knowing who has clear jurisdiction over the use of antibiotics in feed. If it is more than one agency, I want to know what the agencies are doing to work together and who is in the lead, and I want to feel confident that the agencies do not forget about this

issue once this hearing is gaveled to a close, and I yield back.

[The prepared statement of Ms. Schakowsky follows:]

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Mr. {Pallone.} Thank you.

Next is the gentlewoman from Tennessee, Ms. Blackburn.

Mrs. {Blackburn.} Thank you, Mr. Chairman, and thank you to those of you who prepared testimony and are here before us today. Certainly this is a topic that all of us are concerned about. Whether or not it should be the topic that is taking the time that we have today and the taxpayers' money, I will add, is a subject of another debate.

And Mr. Chairman, I will have to tell you, as we look at what is rolling out with this new health care law, I think it is very evident to us that that is where our time needs to be spent. When my children were little, and there was an issue in front of them that needed to be addressed, I would always remind them that avoiding the issue did not make it easier to handle the issue in the long term. If you want to address the problem, it is important that you hit it head on, and we are hearing from people of the numerous problems that exist with this health care bill that has been passed by this Congress and signed into law. There is a lot of concern over there over the expansion of agencies. There is tremendous confusion over the implementation or the expected implementation of that bill. There is surprise by taxpayers that benefits are going to be W-2'd back to them on their

health insurance. We are hearing from employers all during the July 4th break as we talked about freedom and the imperative of preserving freedom. We heard from employers who were saying we are so concerned about the cost. Look at what it is going to cost us to provide insurance under this new list of mandates with all of these new agencies, with all of these new directives. That, believe it or not, translates into jobs lost, and the employers are concerned about that. Now, maybe my colleagues across the aisle are not that concerned but I can tell you losing the number of jobs that have been lost in the past 15 months is a tremendous concern. There is talk about rationing. There was a recess appointment. Talk about national security. How about securing the border? That is something that needs attention from this Congress. Definitely that is an issue that is of great importance to the American people.

Now, while the use of antibiotics in animals and the transference of that to humans is important and we are concerned, we know that there is a lack of large amounts of data on this issue. Does it need our attention? Yes. Do we need to keep a focus on this as we go forward? Yes. But what is an imperative right now is that we look at what the people of this country are saying they want us to address, an ill-conceived health care bill that was passed that is a

government takeover of health care and they want to make certain that we tend to getting that off the books. I yield back.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. {Pallone.} Next is the gentleman from Connecticut, Mr. Murphy.

Mr. {Murphy of Connecticut.} Thank you, Mr. Chairman. I am eager to hear more about the subject that we are convened to learn about today, so I will waive my opening statement.

[The prepared statement of Mr. Murphy of Connecticut follows:]

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Mr. {Pallone.} The gentleman from Georgia, Mr. Gingrey.

Dr. {Gingrey.} Mr. Chairman, thank you.

As past hearings have highlighted, we have a potential antibiotic crisis on the horizon. Simply put, we do not have enough new antibiotics in the development pipeline to meet the health care needs of the 21st century. Therefore, I believe it is important for this committee to review the current regulatory structure and promote incentives that will encourage greater antibiotic production. To that end, I look forward to working with my colleagues on both sides of the aisle to achieve this worthy goal and to look forward to the testimony, of course, from our witnesses today.

Mr. Chairman, on another note, following up a little bit from the opening statement of Ms. Blackburn, I am appalled that President Obama used the July 4th recess to appoint Dr. Donald Berwick as the new CMS administrator without allowing a single public hearing. During the health reform debate, this Administration promised the American people that reform would not ration health care. In fact, the White House's own website under the heading ``health insurance reform reality check'' claims to debunk, and I quote, ``the myth that reform will mean a government takeover of health care or lead to rationing.'' According to Dr. Berwick, however, the

question, and this is his quote, ``is not whether or not we will ration care but whether we will do so with our eyes open.'' To be frank, Dr. Berwick's outspoken support of health care rationing is completely at odds with the Obama Administration's statements on whether rationing is good for our country.

In his inaugural address, President Obama said that, and I quote, ``On this day, we gather because we have chosen hope over fear, unity of purpose over conflict and discord.'' In the July 26, 2008, edition of the British Medical Journal, Dr. Berwick chose hope when describing his support for the British health care rationing system and this is another quote from Dr. Berwick: ``The only sentiment I feel for the NHS [National Health Service] that exceeds my admiration is my hope. I hope you will never, ever give up on what you have begun.'' Mr. Chairman, my hope is that we have some clarity on this issue. Either the President and his Administration support or they are opposed to health care rationing. The American people deserve answers, and unfortunately, this recess appointment has stolen those answers from them.

Mr. Chairman, I urge this committee to schedule a public hearing on Dr. Berwick and his plans for our seniors' health care program. Further, given past statements and opposition

to rationing, I believe that the Administration owes us answers to very, very simple questions. Number one: Does President Obama support Dr. Berwick's philosophy on health care rationing, and number two, does President Obama agree with Dr. Berwick's statement that any humane civilization must, again, Dr. Berwick ``redistribute wealth from the richer among us to the poor and the less fortunate.'' Given that Dr. Berwick now runs our seniors' health care program, I sincerely believe the American people deserve a public hearing so we can get answers to these questions, and with that, Mr. Chairman, I will yield back.

[The prepared statement of Dr. Gingrey follows:]

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Mr. {Pallone.} The gentlewoman from the Virgin Islands, Ms. Christensen.

Dr. {Christensen.} Thank you, Mr. Chairman.

For decades, the scientific literature worldwide has shown that non-therapeutic low-dose antibiotic use in farm animals has caused increased resistance in humans yet I understand that in 1977 when FDA attempted to take steps to curtail such use, Congress ignored the research and the effort was lost. So thank you, Chairman Pallone and Ranking Member Shimkus for your attention to this important issue. Under your leadership, I am sure that we are not going to repeat that unfortunate interception, which is resulting in what is now termed a crisis in antibiotic resistance.

I commend the FDA for the draft guidance they have issued this year, and while I think it is a good first step, I think it is up to the Congress to go further and pass H.R. 1449, the Preservation of Antibiotics for Medical Treatment Act. Led by Denmark and Europe, it has been proven that good animal husbandry and judicious use of antibiotics has successfully reduced resistance without adversely affecting industry or profits. This is yet another area where our country is threatening to fall behind, and this is unacceptable, not only in terms of our leadership but because

it places Americans at undue and unnecessary risk. It also has the potential to put our meat and poultry industry at risk. There can be no denying that swift and definitive action must be taken to protect the health of current and future generations as well as to protect the health of our future economy.

I welcome the witnesses and look forward to their testimony.

[The prepared statement of Dr. Christensen follows:]

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Mr. {Pallone.} Thank you, Ms. Christensen.

I have two statements that Mr. Waxman put forward for the record, one from the San Francisco Medical Society and Physicians for Social Responsibility in--well, one from the San Francisco Medical Society, the other from the Physicians for Social Responsibility in Los Angeles regarding the use of antibiotics, and I would ask unanimous consent that these statements be entered into the record. Without objection, so ordered.

[The information follows:]

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Mr. {Pallone.} And then we had another statement from Ms. Schakowsky. There were one or two letters from Ms. Schakowsky that she asked to be entered into the record, and I would ask unanimous consent that those also be entered into the record. Without objection, so ordered.

[The information follows:]

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Mr. {Pallone.} And next is the gentleman from Michigan, our chairman emeritus, Mr. Dingell.

Mr. {Dingell.} Mr. Chairman, I thank you for your courtesy and I commend you for the hearing.

Today's hearing is the third in a series of hearings on the emerging public health threat posed by antibiotic resistance. The specific focus of this hearing has proven to be the more controversial aspect of the concern raised by public health experts. Its controversy spends decades and very frankly some very serious and important answers are required.

I introduced legislation on this topic in 1980, the Antibiotics Preservation Act. That bill would have directed the Secretary to designate antibiotic drugs which may or may not be used in subtherapeutic doses in animal feed or ingredients of animal feed unless such use is required to meet a compelling need. Interested parties expressed very passionate opinion on the legislation during hearings that year. I remember being troubled by the efforts of FDA Commissioner von Eschenbach in 2007 to approve use of certain antibiotics of last resort in food-producing animals. While there is substantial disagreement between major parties on the magnitude of the problem and the proper approach, I

believe all sides would generally agree on two things. One, antibiotic resistance is a growing public health threat. According to the Infectious Diseases Society of America, about 2 million people across bacterial infections in U.S. hospitals each year. Ninety thousand people die as a result. About 70 percent of these infections are resistant to at least one drug.

It appears the injudicious use of medically important antimicrobial drugs in animal agriculture increases the level of antimicrobial resistance in animals and humans. A variety of scientific committees, task forces and organizations including a number of government organizations have studied the issue. The general conclusion drawn from these studies is that the injudicious use of antimicrobial drugs is not in the interest of protecting and promoting human health, and while that includes many different things, it is a warning to us.

While we can agree on these two points, there is a great deal of uncertainty as to how to address this critical issue and getting proper information on this matter is necessary to properly address it. We must not take for granted the current authority that rests in the Food and Drug Administration to responsively address this matter. I was encouraged by recent actions in that agency, specifically the

issuance of a draft guidance, and look forward to updated programs in their work in other areas including the development of new antimicrobials.

I hope today's hearing will provide some interest on a few critical questions that come to my mind. First, is the problem best solved by a one-size-fits-all approach or should the impact of each drug be separately considered? Two, are additional authorities and resources justifiably needed to fully address the problem? I might just observe, I think so. Three, do the benefits of curbing the use of antimicrobial drugs outweigh the risk of doing so? Four, what data should be reasonably required of regulators to justify future action on the use of antimicrobials in animal feed? And lastly, how do we define judicious use in a way that removes all ambiguity and helps us attain our public health goals while not impairing our other concerns about animal health and about the business of agriculture? I believe the answers to these questions will guide us as we seek ways to address the problem we have before us. Our attempt to address the problem should not be rushed. It must be based on sound science and good information. It must be done in a way that protects both human and animal health, and it should not unnecessarily disrupt the animal agricultural community.

I look forward to hearing the views and thoughts of our

witnesses this afternoon. I am especially interested in hearing the views of our agency experts on this matter.

Again, Mr. Chairman, I thank you for this and I commend you for your leadership. I yield back the balance of my time.

[The prepared statement of Mr. Dingell follows:]

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Mr. {Pallone.} Thank you, Chairman Dingell.

Next for an opening statement, the gentleman from Pennsylvania, Mr. Murphy.

Mr. {Murphy of Pennsylvania.} Thank you, Mr. Chairman, for holding this hearing.

For decades, doctors have known that the widespread use of antibiotics is going to speed the development of bacterial mutation in antimicrobial resistance but what we don't do is give antibiotics to every schoolchild just to prevent infection.

Today, 70 percent of all health care-associated infections in the United States are resistant to at least one antibiotic. These infections cost some $50 billion a year. One antibiotic-resistant infection, MRSA, kills more people in the United States every year than HIV/AIDS. But what would happen if it finally becomes resistant to the few remaining effective antibiotics?

Of course, this resistance is not limited to human health. The vast majority of evidence for the last three decades points to linkage between routine low-level antibiotic use in food animals and the transfer of antibiotic-resistant bacteria to people, often through the food supply. The American Medical Association, the American

Academy of Pediatrics, the American Public Health Association and the American College of Preventive Medicine have all called for a significant reduction in the amount of antibiotics we use in food animal production. Antibiotics have four purposes: to treat disease, control the spread of disease once an infection has occurred, prevent disease from occurring and promote the growth in animals.

Last month, the FDA issued guidance to drug makers, animal farmers, veterinarians that represents a step toward ending antibiotic use for growth promotion and increasing veterinary oversight of animal antimicrobial drugs that are available over the counter at feed mills. Some drug makers are already moving in this direction, and I encourage pharmaceutical companies, farmers and the FDA to keep working together to limit any unnecessary use of antibiotics.

I look forward to hearing from the FDA and other witnesses of how they intend to ensure that disease prevention does not become growth promotion by another name. There are other solutions out there that will keep our food supply safe, our society healthy and our antibiotics effective, and I hope this hearing today will awaken our colleagues to the very real threat to public health posed by the declining effectiveness of antibiotics. Any use of antibiotics anywhere can cause bacteria to select for

resistance but overuse and misuse of antibiotics simply gives bacteria an environment-rich situation to develop resistance and multiply.

To really cut health care costs, save lives and preserve the effectiveness of these vital drugs, we have to eliminate unnecessary antibiotic use everywhere we find it, in hospitals, nursing homes, the general community and sometimes even on the farm.

With that, I yield back.

[The prepared statement of Mr. Murphy of Pennsylvania follows:]

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Mr. {Pallone.} Thank you, Mr. Murphy.

The gentleman from Ohio, Mr. Space.

Mr. {Space.} Thank you, Mr. Chairman.

We have before us a public health issue of significant importance. Studies have indicated the antibiotics upon which our doctors and hospitals relied are losing their effectiveness in treating very serious illnesses. This resistance is a very real problem and indeed a very scary one. Our committee is right to investigate it and right to consider potential solutions.

I am, however, worried about some of the discussions relating to limiting the use of antibiotics in the agricultural setting. My Congressional district is home to a significant agricultural industry which directly employs over 17,000 people and countless more indirectly. It is the linchpin of our economy and an industry easily affected by regulation here in Washington, D.C. Many of the farmers in my district rely on the use of antibiotics to keep animal populations healthy and run productive businesses. And while we must be mindful of the importance of equipping farmers and veterinarians with the tools they need to treat animals when they are sick, obviously we all have to be mindful of the strategic necessary of preventing illnesses from spreading.

Today's witnesses offer a variety of opinions on this issue, many of which take different approaches to the same issue. I look forward to the testimony and to learning more about their perspectives. I believe it is critical that we study the evidence further and take into account all options and all sides of the issue before deciding whether to move forward. If the committee does decide to move forward on this issue, it is my hope we will move in a moderate and bipartisan fashion while working with stakeholders in the agricultural industry. This issue is an important one and worthy of careful consideration, and we must be vigilant in ensuring that the policies we create are carefully thought out.

And with that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Space follows:]

********** COMMITTEE INSERT **********

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Mr. {Pallone.} Thank you, Mr. Space.

The gentleman from Iowa, Mr. Braley.

Mr. {Braley.} Thank you, Chairman, for holding this important hearing on the use of antibiotics in animal agriculture, and I also want to thank all the witnesses who came here today, and I hope that we can have a meaningful conversation on this issue.

Most Americans when they go into a supermarket and buy some pork or chicken or beef have no idea where that food came from how or how it wound up in the supermarket or in their kitchen. A lot of public health officials have never been to a farm and seen with their own eyes and talked to production people involved in agriculture about how that food is taken care of and how it is grown and how it is processed and how it is shipped off to the packing house where it is ultimately dealt with and sent to their table.

A lot of parents take their kids into doctors' offices and demand the use of antibiotics for something that won't even respond because it is a viral infection. We are a culture that looks for simple, easy answers when oftentimes we are talking about complex tradeoffs, and it is no different here talking about the very real public health concerns about antibiotic resistance and very real production

concerns about food safety and food supply.

When I was a student at Iowa State University, it was a well-known accepted fact that it was more difficult to get into the Iowa State Veterinary Medicine College than the University of Iowa College of Medicine, and yet we seem to think that public health research is somehow in some way more superior than animal veterinary research even though oftentimes they come from the same raw data.

So my hope for this hearing is that we can all agree on some fundamental things: A, that antibiotics are essential for fighting bacterial infections in humans, and yet there is still significant disagreement in some sectors about the specific relationship between the use of antibiotics in feed products as they relate to consumption of food and how that affects antibiotic resistance in humans. I have always been an advocate for science-based approach and I think this is an issue that demands careful, thoughtful consideration of all scientific points of view. Rather than come to conclusions based upon ideology, I think we need to look through the entire body of research available. There many well-intentioned people on both sides of this debate, and my hope is, we can continue to have meaningful discussions around tables like this, talk about the best forward to move forward to make sure we continue to have a safe, reliable food supply

and are doing everything we can to protect human health. We need to continue to assess how antibiotics are being used in animals but also across the spectrum in ways that they are being abused and creating the type of antimicrobial resistance we are seeing today, and we also need to make sure that as we listen and learn from the witnesses who have come here today, we continue to fund the necessary research to get to the bottom of how these problems relate to one another and how we make the best informed decisions to protect the public health interest.

So I want to thank you all for being here today. I look forward to your input, and I yield back.

[The prepared statement of Mr. Braley follows:]

********** COMMITTEE INSERT **********

Mr. {Pallone.} Thank you.

And we also have the gentleman from Georgia, Mr. Barrow.

Mr. {Barrow.} I thank the chairman.

I can add nothing to the comprehensive statement of my colleague, Mr. Braley, so I will waive an opening.

[The prepared statement of Mr. Barrow follows:]

********** COMMITTEE INSERT **********

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Mr. {Pallone.} I thank the gentlewoman.

That concludes our opening statements so we will now turn to our first panel. I want to welcome you. Let me introduce each of you. First on my left is Dr. Joshua Sharfstein, who is the Principal Deputy Commissioner for the Food and Drug Administration. And then we have Dr. John Clifford, who is Deputy Administrator for Veterinary Services, Animal and Plant Health Inspection Service for the Department of Agriculture, and finally is Rear Admiral Ali Khan, who is Assistant Surgeon General, Acting Deputy Director of the National Center for Emerging and Zoonotic Infectious Disease with the Centers for Disease Control.

I think you know the drill, 5-minute opening statements. And I should mention, I guess we are expecting votes, but I am going to proceed and then we will see. We may have to-- well, we will have to interrupt at some point but I think we might as well start with Dr. Sharfstein.

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^STATEMENTS OF JOSHUA SHARFSTEIN, M.D., PRINCIPAL DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; JOHN CLIFFORD, D.V.M., DEPUTY ADMINISTRATOR, VETERINARY SERVICES, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE; AND REAR ADMIRAL ALI S. KHAN, M.D., M.P.H., ASSISTANT SURGEON GENERAL, ACTING DEPUTY DIRECTOR, NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASE, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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^STATEMENT OF JOSHUA SHARFSTEIN

} Dr. {Sharfstein.} Good afternoon, Chairman Pallone and Ranking Member Shimkus and members of the subcommittee. I am Dr. Joshua Sharfstein, Principal Deputy Commissioner of the Food and Drug Administration, an agency of the Department of Health and Human Services. Thank you for holding this hearing. Thank you for the opportunity to discuss FDA's role and work with respect to antimicrobial resistance, and we appreciate your leadership.

In my testimony, I will describe FDA's actions to combat resistance and discuss the newly released draft guidance entitled ``The Judicious use of medically important

antimicrobial drugs in food-producing animals.''

As I will discuss in more detail later, in the draft guidance FDA concludes that the overall weight of evidence to date supports the conclusion that using medically important antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health. Developing strategies for reducing antimicrobial resistance is critically important for protecting both human and animal health, both of which are very important to scientists and regulators at the FDA.

Antimicrobial resistance is being addressed on a number of fronts. Dr. Khan from CDC will talk about the data associated with human resistance as it relates to antimicrobial use, and his agency's leadership in efforts to fight resistance in human medicine, but I do want to make a comment as a pediatrician.

I remember vividly in 1998 when I was a pediatric resident and the Centers for Disease Control and the American Academy of Pediatrics published principles for the judicious use of antibiotics in common pediatric infections including the common cold, ear infections, sinusitis and sore throat. I remember giving conferences on the basis of that and I remember the format of the papers and how they printed off the computer. Children have many infections, and as

Congressman Braley mentioned, there was a big issue of parents coming and expecting antibiotics, and these were very strict guidelines for pediatrics on when to use antibiotics and when not to. There was a major effort in pediatrics starting around that time to reduce prescribing, to reduce antimicrobial resistance, and it had an impact. A recent study in the Journal of the American Medical Association showed that antibiotic prescription rates for children under 5 with respiratory infections decreased by 41 percent between 1995 and 2005. That study was published last year.

Many centers at FDA are addressing the public health concern about antimicrobial resistance including the Device Center, which works on diagnostics, the Biologic Center, which works on vaccines, the Drug Center, which works on Drugs. Because today's hearing focuses on antimicrobials in agriculture, I want to talk about the efforts at the Center for Veterinary Medicine.

Our efforts start with surveillance through the National Antimicrobial Resistance Monitoring System. CVM works with CDC and USDA in overseeing surveillance of resistance in multiple areas. In addition, CVM has an approach for assessing resistance associated with the use of drugs intended for food-producing animals. There was a guidance issued, Guidance 152, which explains an approach when there

is a new product coming onto the market, how we assess whether there is a risk from antimicrobial resistance and how that translates into our regulatory pathway.

However, many antimicrobial drug products that were approved prior to the implementation of this guidance have not been evaluated, and a particular concern are those antimicrobials that are considered medically important drugs, meaning those that are important in human medicine and are approved in food-producing animals for production or growth-enhancing purposes.

To address this concern, the Center for Veterinary Medicine released a guidance, as you have heard, on June 28. This is intended to inform the public of FDA's thinking on this issue and to minimize resistance by outlining broad principles for assuring that medically important antimicrobial drugs are used judiciously in animal agriculture. The draft guidance reviews major public health reports on this topic including reports by the Institute of Medicine, the Government Accountability Office, the World Health Organization and its affiliated agencies. Those reports include multiple peer-reviewed studies conducted around the world including in the United States.

Based on this evidence, in this draft guidance FDA recommends phasing-in measures that would, one, limit

medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health, and two, include veterinary oversight or consultation. These steps would help reduce overall use of medically important antimicrobial drugs and reduce the selection pressure that generates antimicrobial resistance.

Prior to issuing the draft guidance, FDA consulted with a wide variety of stakeholders. We spoke with CDC and USDA and got their input on the recommendations. I visited a farm in southern Illinois, which was a very interesting experience, and we are committed to working with all stakeholders across the spectrum, our sister agencies as we get comments from the public on the right way to implement this policy. We are seeking comment through August 30, 2010, and we look forward to a very productive dialog to figure out a very sensible path through this issue that promotes both human and animal health. Thank you.

[The prepared statement of Dr. Sharfstein follows:]

********** INSERT 1 **********

Mr. {Pallone.} Thank you, Dr. Sharfstein.

Dr. Clifford.

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^STATEMENT OF JOHN CLIFFORD

} Dr. {Clifford.} Good afternoon, Chairman Pallone and Ranking Member Shimkus and other members of the subcommittee. My name is Dr. John Clifford and I am the Deputy Administrator for Veterinary Services with the Department of Agriculture's Animal and Plant Health Inspection Service. In this position, I also serve as the U.S. Chief Veterinary Officer for animal health.

Today the subcommittee is looking at an important issue that has far-reaching consequences for human and animal health. USDA believes that it is likely that the use of antimicrobials in animal agriculture does lead to some cases of antimicrobial resistance among humans and in animals themselves, and we believe that we must use medically important antimicrobials judiciously. USDA is committed to playing an active role in preserving the effectiveness of medically important antimicrobials.

USDA believes that policy decisions must be science-based and will provide research to inform the debate. To do this, USDA will work with our federal partners including those at this table.

What constitutes judicious use and how it applies is a

central question to this debate. This must be answered with a sound scientific evaluation and with data-based decision-making. USDA is working to conduct surveillance and research and a number of agencies within the Department are actively engaged on projects to better understand the issue. My written statement details many of these efforts.

Beyond my department, FDA has an existing process for completing risk assessments concerning the use of antimicrobials. USDA believes that this process provides a rational, science- and data-based approach to making decisions about specific antimicrobial use. This is preferable to the approach that broadly eliminates antimicrobials for specific uses.

As we move forward, we must carefully address what current research says and identify gaps in our scientific knowledge. We are committed to working with our federal partners as we have been on these important issues. We need more data so that the policy can properly balance risk between animal and human health needs.

USDA is also looking to expand its existing partnership. For instance, USDA is interested in expanding our work with HHS to improve outreach with veterinarians in the animal agriculture community. We need to work together to conduct research and develop new therapies that protect and preserve

animal health without increasing the risk of resistance to medically important antimicrobials.

USDA is also interested in making our veterinary experts available to provide guidance and share information with veterinarians and producers. This Nation's farmers and ranchers want to do the right thing. If we provide them with the resources and information so they can make informed decisions, they will do the right thing.

Mr. Chairman, I can assure you that USDA recognizes the challenges of antimicrobial resistance and that the entire Department is taking these challenges very seriously. We are committing to ensuring that medically important antimicrobials are used judiciously, which will preserve both human and animal health.

I will be happy to answer any questions that you or your members of the committee may have. Thank you.

[The prepared statement of Dr. Clifford follows:]

********** INSERT 2 **********

Mr. {Pallone.} Thank you, Dr. Clifford.

Dr. Khan, or Admiral Khan, I guess.

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^STATEMENT OF ALI KHAN

} Admiral {Khan.} Good afternoon, Chairman Pallone, Ranking Member Shimkus and other members of the subcommittee. I am Ali Khan from CDC, and thank you for the invitation to address the subcommittee today.

Antimicrobial agents are used to treat infection by different disease-causing microorganisms. Resistance occurs whenever and wherever antibiotics are used, in the community, on the farm or in health care settings. Antibiotics are a subset of antimicrobials used specifically to fight bacterial infections. Many of the bacteria in our food that cause human disease are also in food animals. These healthy food-producing animals commonly carry bacteria in their intestinal tract and they can cause disease in humans including Salmonella and Campylobacter are two examples. Today I will focus on the human health impact of antibiotic-resistance bacteria as they relate to food animals.

There is unequivocal and compelling evidence that the use of antibiotics in animals leads to the development of drug-resistant bacteria that have adverse impacts on human public health. This has been demonstrated for numerous production animals--pigs, cattle, poultry--for numerous

pathogens--Salmonella, E. coli, Campylobacter enterococcus--and in numerous countries--Denmark, England, Spain, Canada, and right here in the United States. Antibiotic-resistant pathogens move through the food supply, so use of antibiotics in animals results in resistant bacteria in food animals. These resistant bacteria then can be present in the food supply and be transmitted to humans. And finally, these resistant bacterial infections can result in adverse human health consequences such as increased hospitalizations or potentially death.

Please allow me to describe some specific examples. Let us see if slide one works here. Can somebody bring up the first slide potentially?

Mr. {Pallone.} Do we have technicians here? Oh, there you go.

Admiral {Khan.} Let us go to the next one. Perfect.

[Slide.]

So Campylobacter is one of the leading causes of foodborne bacterial disease in the United States. It causes approximately 2 million cases per year. And studies have unequivocally demonstrated movement of resistant pathogens through the food supply linked to antibiotic use in animals. So what you can see nicely in this slide to the far left is antibiotic--well, that depends on what side of the screen you

are looking at, to the far left of the slide. There is probably less than 1 percent resistance in those bacteria, and then following the use of fluoroquinolones and the licensing for fluoroquinolones in poultry, what you can see is a dramatic increase starting 2 to 3 years later that has persisted despite a decision by FDA a couple of years ago to stop the use of fluoroquinolones.

Now, this failure to see a subsequent decline in resistance really is a cautionary tale for us and it suggests that the movement of resistance from animals to humans should be considered a sentinel event and demonstrates that resistance once it occurs may not be easily reversed and that prevention is a much better strategy that a control strategy.

[Slide.]

The next slide shows similar data in the United Kingdom. Again what you can see is introduction in the yellow box of a type of quinolone antibiotic in animals and then the increase shows, the increase in resistance, not just in a number of different animal species but in humans also.

And then finally, the Canadian data, which is really quite dramatic, published this year from Quebec, and what this shows is changes in cephalosporins. This is a common antibiotic that we use, changes in cephalosporin resistance in chicken and human Salmonella and chicken E. coli strains

that appear to be related to changes in the use of a type of similar antibiotic in animals, and what you see is a marked decline in those resistance in the E. coli and the Salmonella following a decision for voluntary reduction of the antibiotic in animals, and what is not on this slide is, if you follow out to 2, 3 years, there was a limited reintroduction of that antibiotic for animals, and you see a little spike again as the antibiotic is reintroduced. So very nice, clean evidence of what happens. You introduce the animal. You reduce the antibiotic into the animal population and increase in resistance, and then some examples of a decrease in resistance associated with discontinuing the antibiotic in animals.

Now, studies in Europe have also demonstrated the most compelling and direct links between non-therapeutic use, often referred as subtherapeutic use or use for growth promotion, et cetera, in food-producing animals and subsequent antimicrobial resistance in humans. So the ban of growth promoters in Denmark has prevented spread of vancomycin-resistant enterococcus in humans, reduced resistance in pathogens like Campylobacter and reduced serious human infections, for example, due to specific types of resistant Campylobacter, and this conclusion has been independently verified by the World Health Organization.

Finally, antibiotics are a critical in our Nation's defense against infectious diseases and we need to take strong measures to make sure that we maintain their effectiveness. This subcommittee and my colleagues at HHS and USDA have focused on elements of a comprehensive strategy to protect public health by avoiding resistance that stems from the overuse of antibiotics in animals. Consistent with this one health approach to the prevention of infectious diseases, CDC supports these efforts to minimize non-judicious use of antibiotics in both animals and humans for better human health, animal health and environmental stewardship.

Thank you again for the invitation to testify today and I will be happy to answer any questions.

[The prepared statement of Admiral Khan follows:]

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Mr. {Pallone.} Thank you very much. I thank all of you.

We have three votes, the last votes of the day, about half an hour or so, and so we are going to stand in recess.

Mr. {Shimkus.} Mr. Chairman, will you yield for a minute? During the break, could we ask the majority since those slides weren't provided as far as I know in the testimony, that we get copies of those slides?

Mr. {Pallone.} Yes, we will get copies for you.

Mr. {Shimkus.} Thank you.

Mr. {Pallone.} So we will stand in recess.

The {Chairman.} Mr. Chairman, before we break, may we renew our unanimous consent request to put the--

Mr. {Pallone.} I am sorry, Mr. Chairman.

The {Chairman.} Oh, we did it already?

Mr. {Pallone.} They have all been entered including Ms. Schakowsky's. They have all been entered.

Mr. {Shimkus.} I was all over it for you.

Mr. {Pallone.} The subcommittee stands in recess.

[Recess.]

Mr. {Pallone.} The subcommittee hearing will reconvene. We are going to have questions now, and I will start with myself for 5 minutes.

This is sort of--I am going to cover all three of you with this. I will start with Dr. Sharfstein.

At the end of last month, as you mentioned, the FDA released a draft guidance on the judicious use of medically important antimicrobial drugs in food-producing animals, and as I understand it, the guidance essentially says that antibiotics that are important for treating human disease should not be used in animals except as needed to assure their health, and it also says that veterinarians should be involved when the antibiotics are used for that purpose. So I guess my point is to note that today medically important antibiotics, whether important for treating people or treating animals, are used for non-therapeutic purposes, and so many of the people who use them for those purposes, Dr. Sharfstein, haven't necessarily reacted to your guidance in a positive way.

So my questions are about the scientific basis for the guidance. What led you to develop the guidance? Did you meet with stakeholders such as industry that would be affected by the policies? What has been the general reaction to the guidance? Who supported it? Who has opposed it? I mean, we know that the producers aren't happy about it. On the day your guidance was released, the president of the National Pork Producers Council said FDA didn't present any

science on which to base this. So that is my question, really, is it scientifically based? What is your response to the naysayers?

Dr. {Sharfstein.} Well, we look forward to the comment period and we will review everything that we get from different groups officially. I actually have been impressed at the interest across many different areas of the animal agriculture in working with FDA and I will note that the Animal Health Institute, that they welcome the guidance, and the AVMA said that they were pleased that we are committed to working with the veterinary profession to address antimicrobial resistance concerns.

So I think it may be--you know, I wouldn't necessarily buy into us versus them on this. I think that is a very sensible path. It really rests on a mountain of strong science, and one of the documents we cite, I think is really excellent. It is the WHO 2003 report which walks through six lines of evidence that exists, citing multiple studies including a number done in the United States, and the six are outbreak investigations which trace Salmonella infections to farms, epidemiological investigations which demonstrate that people are more likely to have visited or lived on a farm prior to illness, that they have antimicrobial-resistant infections, field studies including some I think you will

hear about on the next panel where they actually prospectively demonstrate how antimicrobial use in food animals selects for the emergence of resistance, case reports including children who have been sick, spatial and temporal associations where countries where they use less antimicrobial agents you see less antimicrobial resistance in bacteria, and finally, molecular subtyping, so this is the sixth type of evidence, and I will be happy to submit this to the record--it is cited in our report--where you actually can trace the specific bacteria around, and they find--and one of the studies I found most interesting, I think it was from Minnesota, is that the resistant strains of the bugs in humans match the resistant strains in the animals and those match the sensitive strains in the animals except for the resistance genes, but the sensitive strains in humans don't match those. So you think it basically looks like the resistance is coming from the animals and the animal resistance is developing in the animals, and they do that by molecular analysis of the actual bacteria.

So I really do think there is a very strong foundation of evidence. I think Dr. Khan--

Mr. {Pallone.} Well, let me ask the other two guys.

Dr. Khan, do you agree with Dr. Sharfstein on this, and Dr. Clifford, do you believe that growth promotion is an

injudicious use of antibiotics? Basically if you would comment.

Admiral {Khan.} CDC supports the FDA position. The position is consistent with the one health approach and essentially how we use antibiotics for human use, and a number of members of the committee have pointed that tout. So we use antibiotics in humans specifically for treatment, for prophylaxis when it is a specific targeted individual or targeted drug for targeted indication, and those are the three uses in antibiotics. So, you know, I have kids in daycare, and lots of them are infected with all sorts of things. Nobody would ever propose that all children in daycare, for example, should be on antibiotics through that whole time frame. So this is very consistent with the one health approach and how we deal with antibiotics in humans.

Mr. {Pallone.} Dr. Clifford?

Dr. {Clifford.} We work very closely with FDA in consultation with this document and provided feedback to them. We think this is a good first step, and we welcome seeing the comments as well that FDA receives on this particular document.

As far as whether growth promotion or judicious use of antibiotics, our position is that with regards to judicious use of medically important antibiotics, we are talking about

treatment, control and prevention of animal health issues and disease. So there are antibiotics, though, that are used, or antimicrobials that are used in animals that have no analog being used in human medicine and should not be of concern unless there is proven evidence to the human side.

Mr. {Pallone.} Okay. Thank you all.

Mr. Shimkus.

Mr. {Shimkus.} Thank you, Mr. Chairman.

Dr. Clifford, is there science to support the removal of antibiotic use for growth promotion?

Dr. {Clifford.} I am sorry?

Mr. {Shimkus.} Is there science to support the removal of antibiotic use for growth promotion?

Dr. {Clifford.} You mean as far as the cause and effect?

Mr. {Shimkus.} Right.

Dr. {Clifford.} There is some cases.

Mr. {Shimkus.} Well, can you cite them?

Dr. {Clifford.} Well, obviously you can cite the Danish experience.

Mr. {Shimkus.} No, I am talking about United States.

Dr. {Clifford.} Not right offhand, no, I cannot.

Mr. {Shimkus.} Do you know of any U.S.-supported research peer review?

Dr. {Clifford.} I cannot cite any.

Mr. {Shimkus.} You are similar to other testimony we received in April where Dr. Fauci and also quoted Dr. Frieden, and this is the hearing record. ``To my knowledge and to Dr. Frieden's knowledge, I don't think any of those studies have been done in the United States.''

I mean, I saw Dr. Sharfstein give you a note. The question is for you, not for Dr. Sharfstein. Dr. Sharfstein, I will ask you questions if you have--with my time available.

Equating animals to people is like equating an apple to an orange. I am just--that is why we have vets and that is why we have doctors. That is why vets are not qualified to work on human beings or medical doctors qualified for animals unless I am sure in parts of southern Illinois years ago but--let me ask Dr. Sharfstein. What decreases in the level of human antibiotic resistance will we see if FDA proceeds with this Guidance 209 document as currently proposed?

Dr. {Sharfstein.} I expect that if we go forward with Guidance 209 as currently proposed that this will reduce antibiotic resistance pressure. We will have less antibiotic resistance in animals and less antibiotic resistance in humans, and it will promote both human and animal health.

Mr. {Shimkus.} And by what percent?

Dr. {Sharfstein.} I don't think I can answer the exact

percentage.

Mr. {Shimkus.} And can you cite me a study, a U.S. study that verifies that analysis and that answer?

Dr. {Sharfstein.} Yes, I can. The Institute of Medicine's 2003 report was very clear that this would be the right approach to take for this reason.

Mr. {Shimkus.} Is that a study and is it peer-reviewed science?

Dr. {Sharfstein.} It is a study, and they do have a peer-review process at the Institute of Medicine. The Institute of Medicine is considered our Nation's leading scientific expert, you know, group. They looked at this issue. They said to do nothing is in effect to allow the continued evolution of antimicrobial-resistant microbes which poses serious and long-term--

Mr. {Shimkus.} And let me--and what do we see as a national government? Have we done any additional research to verify their findings?

Dr. {Sharfstein.} There has also been research in King County related to Campylobacter that is very compelling. There is a New England Journal study from Minnesota that is very compelling. I would be happy to submit all these studies for the record.

Mr. {Shimkus.} We would like them all, please.

Dr. {Sharfstein.} Dr. Frieden mentioned in his letter to the committee that there is extensive data from the United States.

Mr. {Shimkus.} Yes, correcting the record by which he was quoted in April, and we find that curious and also timely that that occurred.

Dr. Khan, I want to go to your slides that you had presented to us, and if the staff could pull up slide number 1 for me from Dr. Khan's. I am sorry. We should have given you a heads-up, but if we didn't, we apologize. That is the right one.

The antibiotics on chart 1 are mostly used for therapeutic use, not subtherapeutic use. Is that correct?

Admiral {Khan.} Yes.

Mr. {Shimkus.} I see that there was no reduction in the little arrow there for those who have it. That is when it has been removed. There was no--in fact, there is an increase after it was removed. What does that say?

Admiral {Khan.} That says prevention is really a lot more important than control, so these may represent sentinel events. The moment you get a resistant bacteria from animals that makes it way into the human population, there is a different set of drivers for maintaining it in humans that makes it impossible to shut it down.

Mr. {Shimkus.} Could it be that there is another cause for the resistance other than for which we are speaking of today?

Admiral {Khan.} I think the data is pretty unequivocal. Before the use of fluoroquinolone--

Mr. {Shimkus.} Well, let us go to the second slide. Let us talk about this unequivocal data here. This is the, I can't pronounce it, quinolone resistance, Salmonella and typhimurium. First question. I was elected to Congress in November of 1996, took office in 1997. This chart ends in 1997, 14 years ago. Is there no data after that?

Admiral {Khan.} There is data after that.

Mr. {Shimkus.} And what does that data show?

Admiral {Khan.} The data shows continued resistance. The purpose of this specific slide was to show that the introduction of this antibiotic into animals led to an increase in resistant bacteria in not just--

Mr. {Shimkus.} I think if you would add data, I think what we can find, and maybe this is why it was not submitted is that you are going to see a decrease, and if that is the case, I find it very perplexing and very troubling that we use data from 1997 and we don't go to 14 years later to show the path.

Mr. Chairman, I know my time is expired, but the last

thing, I also have problems with the third slide. That is the importance of getting data and information here in a timely manner so we can check sources, and to use World Health Organization data, to have dumbed down from the Danish study which will make the Danish products competitive because it is going to make us more difficult to compete. We are dumbing down our ability, is very problematic and I would agree with some of my colleagues, even on the other side, we better go very, very carefully and use real science in this antibiotics use of animals, and I yield back my time.

Mr. {Pallone.} Chairman Waxman.

The {Chairman.} Dr. Khan, just on that last question you were asked, if you had more data, you say it would show the same results as what you saw in 1997?

Admiral {Khan.} It depends on the country, sir. So in the U.K. there is continued persistence. In the United States, using National Antibiotic Resistance Monitoring System, NARMS, which is a system we use with FDA, that FDA, USDA and CDC sponsors, there is variable data for different pathogens that shows either continued increase or for some select Salmonellas decreases in resistance. The reason I used--so the first slide is actually U.S. data, fluoroquinolones in the United States, unequivocal that the moment you use the fluoroquinolones, within 2 to 3 years from

less than 1 percent you went up to 20 percent resistance. That has remained--

Mr. {Shimkus.} Mr. Chairman, I don't want to be disrespectful, but the point is, that is for therapeutic--

The {Chairman.} Just a minute. You are disrespectful.

Mr. {Pallone.} Chairman Waxman has the time.

Mr. {Shimkus.} Well, I was hoping you yield, but I apologize.

Mr. {Pallone.} No, he is not yielding at this time.

The {Chairman.} Go ahead. He doesn't like the answer you are giving but let us hear what it is.

Admiral {Khan.} So that initial data, sir, the fluoroquinolone data is U.S. data. We also have abundant additional U.S. studies showing this. So if we look at Salmonella typhimurium DT-104, multi-resistant outbreak amongst people, that was due to ground beef. If we look at Salmonella Newport, this is a multi-resistant strain--

The {Chairman.} Well, let me ask you this because in USA Today on Monday, the director of the National Pork Producers Council said that, ``According to top scientists with the Centers for Disease Control and Prevention and the National Institutes of Health, there are no scientific studies linking antibiotic use in livestock production with antibiotic resistance in people.'' Is this an accurate

reflection of CDC's views?

Admiral {Khan.} Sir, Director Frieden has submitted a letter to the committee that specifically states that there is a compelling body of evidence to demonstrate this link that is summarized above, so there is multiple North American studies that describe how use of antibiotics in animals results in resistant bacteria in food animals. These resistant bacteria then are present in the food supply and transmitted to humans. And finally, these resistant bacteria can result in adverse human health consequences such as increased hospitalization, and there is good scientific evidence for each one of those three assertions.

The {Chairman.} Well, a large part of the confusion seemed to stem from the question about the adequacy of the peer-reviewed literature showing a link between antibiotics use in animals and resistant infections in humans. Do you think there is substantial scientific evidence demonstrating a link between antibiotic use in animals and infections in humans, and can you discuss the implications of European versus USA data?

Admiral {Khan.} So there is an unequivocal evidence and relationship between use of antibiotics in animals and transmission of antibiotic-resistant bacteria causing adverse effects in humans following that pathway that I have

outlined. The Danish data is also very clear on the use of subtherapeutic use of antibiotics for animals and what the consequences on resistance in humans.

The {Chairman.} Dr. Sharfstein, do you think there is substantial scientific evidence demonstrating a link between antibiotic use in animals and infections in humans?

Dr. {Sharfstein.} Yes, I do think that.

The {Chairman.} And is this scientifically controversial?

Dr. {Sharfstein.} I don't believe so, no.

The {Chairman.} I wanted to ask a different line of questions, and that is regarding, as we consider antibiotic use in animals, we have heard concerns from some of the producers that reducing the routine use of antibiotics in animals could result in increased risk of foodborne illnesses. Since we have representatives of two of the country's leading public health agencies, I would like to ask you about your assessment of the risks and benefits of reducing the use of antibiotic use in animals. I think it is important to understand that no one here is proposing to ban the use of antibiotics for animals. The goal here is to reduce the use of antibiotics that are important to human health and animals, particularly when that use provides little or no benefit to those animals.

Dr. Sharfstein, as you know, it is the mandate of the Food and Drug Administration to ensure that the food supply is as safe as it can be, so would you be concerned if you believed that reducing the use of important human antibiotics in animals could result in increased risk to the food supply?

Dr. {Sharfstein.} Let me make sure I understand your question. Am I concerned or would it be concerned?

The {Chairman.} Are you concerned if you reduce the use of antibiotics in animals that affect humans that this could result in increased risk to the food supply?

Dr. {Sharfstein.} I think with our guidance, we are talking about the use for not-health purposes, so we don't believe if we are eliminating the use for not-health purposes we are going to have adverse health consequences.

The {Chairman.} Is there evidence to support the claim that phasing out certain uses of antibiotics could increase risks to the food supply?

Dr. {Sharfstein.} I think if by certain uses you mean the uses we are proposing phasing out, you know, for growth promotion, feed efficiency, I would say no, there is not evidence.

The {Chairman.} Dr. Khan, you are the Nation's leading epidemiologist at CDC as well as the agency tasked with conducting outbreak investigations foodborne illness. Would

CDC be concerned if it believed that phasing out certain use of antibiotics in animals would increase the risk of illness in humans?

Admiral {Khan.} No, sir, there is no scientific evidence suggesting a negative impact on human health for limiting the non-judicious use of antibiotics in animals.

The {Chairman.} Thank you.

Thank you, Mr. Chairman.

Mr. {Pallone.} Thank you.

Next is the gentleman from Indiana, who has 8 minutes. Mr. Buyer.

Mr. {Buyer.} Thank you very much.

Dr. Clifford, I have a question that deals with adulterated, counterfeit, knockoff drugs. We have a problem in our country, and countries around the world are challenged by this. Do you see any escalation or any evidence of adulterated counterfeit drugs in animal health?

Dr. {Clifford.} Congressman, since this really falls under FDA's jurisdiction, I would have to turn to them to answer that question.

Dr. {Sharfstein.} In the United States--

Mr. {Buyer.} Hold on a second.

Dr. {Sharfstein.} Oh, I am sorry.

Mr. {Buyer.} Hold on. Go ahead. Thanks. For animal

health.

Dr. {Sharfstein.} For animal health, I think we are going to have to get back to you. I am not prepared to answer that. I have not heard of a significant counterfeit problem in the United States but I want to make sure and get back to you.

Mr. {Buyer.} You know, as our problem is growing, it is only time before it migrates. It is going to follow the money, right? Bad guys follow the money. And that is why I asked the question.

I want to thank the FDA for continuing the blitzes that you are doing at international mail facilities, so thank you for doing that. You are trying to ``get the word out'' to Americans that if you go on the Internet and you think that that is an approved website to order your pharmaceutical products, that you are really playing Russian roulette with your life, and so thank you for keeping these blitzes going and trying to get the word out. I noted in your testimony when you were with us in March, you had in your testimony, ``Protecting Americans from unsafe or contaminated drugs is not just an important responsibility of the FDA, it is our core charge.'' Do you agree with that today?

Dr. {Sharfstein.} I do believe that. I think it is one of the reasons that FDA--

Mr. {Buyer.} So--

Dr. {Sharfstein.} --was established.

Mr. {Buyer.} I am sorry?

Dr. {Sharfstein.} I was saying, it is one of the reasons FDA was established.

Mr. {Buyer.} You also then in your testimony talked about FDA must adopt a new approach. Now, I think when you talked about your new approach, also you were concerned about the production, i.e., raw ingredients, that are used within our supply chain for which people are buying at retail outlets within the gold standard of our own country. So ensuring that we maintain that gold standard, you are putting your eyes on that supply chain and production. I don't have any problems with that. I think that is wonderful. I think the Administration is doing what it is supposed to do. I applaud you with regard to your striking the agreements with other countries, putting more inspections on other soils. That is awesome.

With regard to your--it is twofold. Not only do you have that to do but we also have the mail facilities. Now, as we are doing this, we have got both of these going on at the same time, is we are trying to then do our electronic pedigree, and Mr. Dingell has a bill, and we are going to do work and do this electronic pedigree, but let me tell you

what I was bothered about what I read in the Miami Dade about your last blitz. I think it is great. Like I said, you are doing the blitz. You did a 3-day blitz. You did everything you were supposed to do, your coordination with Customs, Border Protection, thousands of pieces of foreign mail. You X-rayed them. You separated them. You identified them, the suspicious pharmaceutical products. You ID'd them. You showed how many of them were counterfeit and knocked off, and then you sent them back. America has to be shocked, and the counterfeiters have to be excited that America is a place where you can counterfeit your drugs, send them to America, steal people's money, and the American government will send the counterfeit drugs back to you so you can then send them to someone else that you can steal more money from. This is like one of the dumbest policies I think we have in this country.

Now, last year I sent questions on this, and the answer from FDA is that FDA currently has authority to seek through the judicial process the destruction of any drug and other FDA-related products that relates to the Federal Food, Drug and Cosmetic Act. Now, the person right next to your inspectors, Customs, I mean, there is no wall. You have been there, right? There is no wall between these guys. That customs person, when they see it identified prima facie as

knockoff, they destroy it. But if they hand off and give to the FDA person, the FDA says we can't destroy it, put a label on it and they send it back. I know you have got to be uncomfortable with that as a policy. Are you?

Dr. {Sharfstein.} Yes. I mean, I have spoken to some of the inspectors who are, you know, as frustrated as you are.

Mr. {Buyer.} All right. Now, if you are willing to step into a new--and that was your testimony that you gave to us in March, that you embrace and wanted to adopt a new approach with regard to the raw ingredients, through production and distribution always to U.S. consumers, I think I have an opportunity. I think, Mr. Dingell, we have an opportunity to help protect America, and that is embrace what the FDA is saying here, Mr. Dingell, and let us figure out how we can destroy these when they are identified, when your inspectors identify them. Let us not send them back to the counterfeiters so they can continue to rip off people. You know, Doc, come on, they are preying upon the most vulnerable of our population, which is awful. Would you be willing to work with Mr. Dingell and I to come up with a policy here that can give your inspectors the ability to destroy these counterfeit, knockoff, adulterated drugs?

Dr. {Sharfstein.} Yes, and I believe we have been

already starting that process by working with your staff and Congressman Dingell's staff on this issue.

Mr. {Buyer.} All right. Well, I want to be as proactive as we possibly can. John Dingell, to his credit, started this a long time ago with his paper pedigree, and he has always had a great interest. It goes all the way back many years into the 1970s, and I applaud what he has done. I think he has got to be pretty shocked on where America is today compared to where we were in the 1970s, and as a policy and I know you adopted this, I was just as frustrated with the last Administration but I am embracing your spirit, and if we are able to move ahead, Mr. Dingell, I want to join with you today and I want to work with the FDA and I want to resolve this matter.

I want to yield to the chairman for a second.

Mr. {Dingell.} I thank the gentleman. He is most kind to me, and I want to thank him for the kind comments he has made about me. I want to assure him that my assurances of the last Congress, I would be happy to work with him, and I happen to agree with the gentleman about the problem of imports, about tracing pharmaceuticals and other drugs, and I am pleased to report to the gentleman that very shortly we will be circulating a draft for comments about pharmaceutical safety, and I hope that the gentleman when that occurrence

happens that he will look at it with sympathy and I look forward to working with him because he is a valuable member of the committee, and I thank him.

Mr. {Buyer.} I thank the gentleman.

The last, can I do this piece of math? Thirteen--

Mr. {Pallone.} The gentleman's time has expired, but all the love--

Mr. {Buyer.} I ask unanimous consent for 30 seconds.

Mr. {Pallone.} Yes, with all the love and bipartisan here--

Mr. {Buyer.} God bless you.

Mr. {Pallone.} I certainly don't want to stop the gentleman.

Mr. {Buyer.} Thirteen international mail facilities, on average 35,000 are pharmaceutical packages, times 365 days, that is 1,666,075 packages a year. If 80 percent are counterfeit, adulterated or knocked off, that means there are 132,860 pharmaceutical packages that are coming into the country that are either adulterated, counterfeit or knockoff, and people are taking these and they are not metabolizing in the body in ways in which as doctors you intend.

With that, I yield back. Thank you.

Mr. {Pallone.} Thank you.

The gentlewoman from--I am sorry. Chairman Dingell is

next.

Mr. {Dingell.} I thank you, Mr. Chairman.

These questions are for all three witnesses. The first is yes or no. Is there a definitive link between antimicrobial use in animal feed and antibiotic resistance in humans? Starting with Dr. Sharfstein.

Dr. {Sharfstein.} Yes.

Mr. {Dingell.} Our next witness, Doctor.

Dr. {Clifford.} Yes, some.

Mr. {Dingell.} Some?

And you, Dr. Khan?

Admiral {Khan.} Yes, sir.

Mr. {Dingell.} Now, Dr. Sharfstein, please tell us what scientific studies support your claim.

Dr. {Sharfstein.} I think the best document that begins to summarize those is this 2003 study from the World Health Organization and it goes through outbreak investigations, epidemiological investigations, field studies, case reports, spatial and temporal associations and molecular subtyping. In each of those areas of research there are studies that support that statement.

Mr. {Dingell.} Now, Doctor, if you would like, I would be pleased to have you make other submissions supporting the statement which you just made.

So next question to all three of our panel members. Are these studies based--rather is to Dr. Sharfstein. Are these studies based entirely on the European experience or do we have some that reflect experience in the United States?

Dr. {Sharfstein.} They are both based on European experience and some that are in the United States including one by someone I went to medical school with.

Mr. {Dingell.} Now, again, Dr. Sharfstein, it is my understanding that FDA currently has authority to withhold approval for certain animal drugs if they are use poses a risk to the public health. Is that correct?

Dr. {Sharfstein.} That is correct.

Mr. {Dingell.} Okay. Now, does the likelihood that an antimicrobial drug used to treat a food-producing animal may cause antibiotic resistance to a problem in humans to pose a risk, and I put the risk to public health in quotes. What is the answer to that? Do you want me to repeat the question?

Dr. {Sharfstein.} Yes.

Mr. {Dingell.} Does the likelihood that an antimicrobial drug used to treat a food-producing animal may cause an antibiotic resistance problem in humans pose a ``risk to public health''?

Dr. {Sharfstein.} I think that the likelihood that that would happen does factor into the regulatory process as we

approve new antimicrobials, so yes.

Mr. {Dingell.} And our other two witnesses, Dr. Clifford and Dr. Khan, what is you view on that question?

Dr. {Clifford.} Could you repeat that question again, please?

Mr. {Dingell.} It is a difficult question. All right. Does the likelihood that an antimicrobial drug used to treat a food-producing animal may cause an antibiotic resistance problem in humans pose a ``risk to the public health''?

Dr. {Clifford.} I still--yes, I mean, it is possible for sure.

Mr. {Dingell.} Dr. Khan?

Admiral {Khan.} Yes, sir, and there is currently ample evidence that use of antibiotics in animals results in resistant bacteria in food animals, resistance is present in the food supply and transmitted to humans and that resistant bacteria result in adverse human health effects. So that data already exists and is summarized in various documents.

Mr. {Dingell.} Now, gentlemen, again, based on this interpretation, and this is to Dr. Sharfstein, based on this interpretation, since 2003 FDA has considered the likelihood for antimicrobial resistance in the drug approval process. Is that correct?

Dr. {Sharfstein.} Yes.

Mr. {Dingell.} Now, has the interpretation been applied to all drugs currently on the market as well as new applications for drugs where the manufacturer is seeking access to the market?

Dr. {Sharfstein.} No, it has just been applied to new drugs coming on, and that is the reasons we would like to do this guidance is addresses some of the issues with the drugs that were already on the market.

Mr. {Dingell.} But you are not dealing with those which are already on the market. All right.

Now, why has this interpretation not been used more widely for those drugs that were on the market prior to 2003? Is it for want of authority by Food and Drug?

Dr. {Sharfstein.} I don't believe it is for want of authority, no.

Mr. {Dingell.} Now, Doctor, what are some of the barriers to new antibacterial drug development and what is FDA doing to help spur innovation in this area?

Dr. {Sharfstein.} I think there are two main barriers to antimicrobial drug development. One of them is the need for clear approval pathways so that companies can design studies that can reach the right endpoints and be approved, and FDA is working very hard to get the science right so we can have those clear approval pathways. There is a meeting

by the end of July that will be the next step in that process.

The second major issue is the issue of incentives for antibiotic development because it is expensive to bring drugs to market, and for antibiotics we don't want them to be used that much when they are there so the market isn't that great, so we believe there is a market issue as well as a pathway issue. FDA is supportive of discussions around the market incentive issue but it is a little bit outside of our sphere to really solve that problem.

Mr. {Dingell.} Thank you.

Mr. Chairman, I have used more than my time. Thank you.

Mr. {Pallone.} Thank you, Mr. Chairman.

Next is the gentlewoman from Illinois, Ms. Schakowsky.

Ms. {Schakowsky.} Dr. Sharfstein, I am trying to understand then what the guidance says. Does it say it will only apply to new drugs?

Dr. {Sharfstein.} No, no. I am sorry. I must have been confused.

Ms. {Schakowsky.} Oh, okay.

Dr. {Sharfstein.} There is a Guidance 152 that only applies to new drugs. I was referring to a guidance that was issued in 2003. I think that was what Chairman Dingell was referring to. This new guidance--one of the reasons that we

are issuing this new draft guidance is because the old one doesn't apply to existing drugs. This deals with some of the issues with existing drugs.

Ms. {Schakowsky.} This would apply to all antibiotics?

Dr. {Sharfstein.} All medically important antibiotics.

Ms. {Schakowsky.} Right. Okay. So we have the FDA, the USDA, the CDC here today. Which agency has lead jurisdiction to ensure then that the public is not at risk from overuse of antibiotics in livestock feed?

Dr. {Sharfstein.} I think FDA has regulatory authority over the use of antimicrobials in animals, but we work very closely with our--

Ms. {Schakowsky.} That was my next question. So how do you coordinate? Is there some sort of a--

Dr. {Sharfstein.} Yes, the President's Food Safety Working Group is one of the places that we have had very good discussions. This issue has been presented in a lot of discussions, and then separate from the big group, we have also worked individually. I think Dr. Clifford and the team at FDA were on the phone multiple times, and certainly CDC was within HHS, we are constantly talking to CDC at FDA.

Ms. {Schakowsky.} The FDA voluntary guidelines address non-therapeutic use, right?

Dr. {Sharfstein.} It addresses what we call production

uses, growth promotion, feed efficiency.

Ms. {Schakowsky.} But I heard that poultry farmers have recently stated that from egg to slaughter, chickens and turkeys always need antibiotics to prevent disease. Now, here is my concern. If you are only talking about non-therapeutic use, what is to prevent farms from re-categorizing the purpose of the antibiotics they give to animals instead of actually ending the overuse?

Dr. {Sharfstein.} Well, I think you are getting to the concept of prevention, how we would approach preventive uses, and what the guidance, the draft guidance states is that it is not enough for someone to say I think this prevents disease, that is not enough, that our approach to prevention has to be based on evidence, and factors to consider include the evidence of effectiveness, the evidence that such a preventive use is consistent with accepted veterinary practice, evidence that the use is linked to a specific microbial agent, evidence that the use if appropriately targeted and evidence that no reasonable alternatives for intervention exist. So if we were going to look at prevention uses, which we do believe are important, can be important for animal health, we would apply kind of a scientific evidence-based set of criteria to that scenario.

Ms. {Schakowsky.} Dr. Khan, are you comfortable with

that as well? Because you talked about prevention being the best thing.

Admiral {Khan.} Very much, ma'am, and this is also consistent with how we use antibiotics in humans for prevention purposes, so a good example is meningococcus. It is a meningitis, inflammation of the brain. We do use it for prevention, a specific drug for prevention purposes, but it is specific to targeted people who get it. You get the drug twice a day for two days for targeted infection. You don't get it forever, and everybody in the emergency room, for example, doesn't get it.

Ms. {Schakowsky.} Let me ask you this. To what extent would it be true to say that the use of antibiotics can be effective in masking unsanitary conditions where livestock is raised? In other words, if you use antibiotics, then you don't have to be quite as precise about the level of cleanliness at places. Is this ever an issue?

Dr. {Clifford.} Production management with regards to farms and location of animals, that type of thing could be possible but that is not a good management use of animals and it is not going to lead to their bottom line economically. If they run poor sanitation on a farm and have to use antibiotics to offset that, they are taking away cost and dollars from their operation, and the bottom line with

production agriculture, it is economics. I mean, they are raising food and--

Ms. {Schakowsky.} But let me--can I ask one quick question?

Dr. Sharfstein, the guidance has no enforcement component. How can we be sure that it will have any effectiveness at all?

Dr. {Sharfstein.} Well, the way we think of this is not much as a guidance or regulatory document, this we kind of put out as a white paper. This is sort of the foundation for how FDA intends to move in this area, and then it is basically like a foundation for us to build on. We have had some productive discussions with the various components of the animal agriculture industry and we expect that we will be seeing movement in this direction by their good efforts and I think their comments in response to the guidance indicate that, but I also think that as we move forward under this kind of framework, we will be open to the idea that we will then have to, you know, consider regulatory options. So this was not intended as a regulatory document. It was really intended as a here is what the science says, here is the right direction to move in, and really let us get comments on how to do this as well as possible with the minimal impact on agriculture and let us do it effectively, but we are going to

see what we can get from setting this vision and then we are going to consider other things.

Ms. {Schakowsky.} This is really a health hazard. It all sounds real slow but I hope that we will have a progress report that will show some movement before too long. Thank you.

Thank you, Mr. Chairman.

Mr. {Pallone.} Thank you.

The gentlewoman from the Virgin Islands, Ms. Christensen.

Dr. {Christensen.} Thank you, Mr. Chairman, and thank the panelists. I really thought I had missed this first round of questioning with the panel but I am glad I didn't.

Just maybe three questions. Dr. Sharfstein, welcome back.

Dr. {Sharfstein.} Thank you.

Dr. {Christensen.} The FDA should now be implementing and receiving--I apologize if this question was asked--and receiving more detailed animal drug sales data under the Animal Drug User Fee Act Amendments that was signed into law in 2008. Has any data started coming in?

Dr. {Sharfstein.} Yes, we have started to get data.

Dr. {Christensen.} I am concerned that we don't seem to have a method in this country to track actual usage of these

drugs in animals that become food. Is that concern warranted, and if so, when would be able to review an analysis of this new data to see whether additional reporting requirements might be necessary?

Dr. {Sharfstein.} Well, first, we are starting to pull together the data. We are just getting--I don't think we have a complete set yet. I am not 100 percent sure about that, but I know that we are just sort of pulling it together, and I don't think it will be too long before we will be able to share some of that information. But I think to your point, I think you are exactly right. The data under ADUFA is just part of it. It is overall sales and a little bit by particular use, but it doesn't really tell you how the antimicrobials are being used. It is not the kind of data, for example, that we might get about pediatric practice and pediatricians' use of antimicrobials, and so I think that one of the things that we have been talking about, and there is a meeting very shortly in NARMS coming up is that there is a need for a better surveillance system and that is something where we hope to work very closely with USDA on.

Dr. {Christensen.} Thank you.

Dr. Khan, we talked a lot about the antibiotic resistance in animals and the fact that it creates resistance in humans but how do people become exposed to antibiotic-

resistant bacteria through the food supply? Is it by eating contaminated meat and poultry or can cross-contamination become a problem? And does cooking resolve the problem? Could you just clarify for us how that happens?

Admiral {Khan.} Yes, ma'am, I would be glad to. There are multiple mechanisms by which resistant bacteria in animals can make their way into humans. The first is the most obvious. That would be the direct transmission or the direct route, and that would be directly from animals to humans, and we see that--

Dr. {Christensen.} Just from contact working with animals?

Admiral {Khan.} Direct contact, and we see that reported all the time. The second mechanism within that direct route is from food, so contamination of food that subsequently you are handling and you become infected. So we see that route as the direct route. There is also the indirect route of transmission, and this is where specific genetic material within a bacteria of animals can move into bacteria of humans and that resistance, so although the bacteria in animals doesn't move to humans, the resistant pattern moves into humans and then can cause human resistant bacteria.

Dr. {Christensen.} Thank you for that clarification.

And Dr. Clifford, if funds were available, would the USDA be willing to initiate a pilot program where producers could receive assistance for transitioning to antibiotic-free methods and where results could be collected and reported?

Dr. {Clifford.} I think one of the issues that is out there is the lack of evidence of cause and effect when you remove these things, so I think it would be important to look at some of these types of things from the standpoint of a pilot project but also from the standpoint of the development of other methods and working with industry and such as vaccine development and other technologies to be able to better address this issue.

Dr. {Christensen.} So do you have other priorities such as vaccines? New vaccines would be a higher priority than--

Dr. {Clifford.} I am not saying which one would be the highest priority but I think all those things need to be looked at, and I think we as a body within the federal agencies need to be identifying, sitting down and working with the industry and others to identify the highest priorities and identify the way that we can best use our resources to address those.

Dr. {Christensen.} In your testimony, you say that animal impacts must be considered in the context of the decision-making process. Does that mean that there is some

tension between USDA and FDA over the approach or are you all on the same page?

Dr. {Clifford.} Well, I think in general concept, we are on the same page. I mean, it is not that FDA and USDA are going to agree on every particular issue. I think it is important to note that as we all know, this is an extremely complex issue. My role as chief veterinary officer is the protection of animal health. Obviously I care very much about public health as well. So I think we have got to look at all of these things and balance these things, and this is a very complex issue and we don't believe that one size fits all.

Dr. {Christensen.} Thank you for your answers.

Thank you, Mr. Chairman.

Mr. {Pallone.} Thank you, Ms. Christensen.

Thanks a lot. Unfortunately, we are interrupted with two sets of votes today but I appreciate your bearing with us and also changing the date which we did on you a few weeks ago, so this is very helpful. Now, we will likely send additional questions in writing within the next 10 days or so, but I appreciate your being here today. Thanks so much.

Marathon panel coming up here. Let me welcome the second panel. I hope you have enough room there kind of squeezed in. Let me introduce each of you. Starting on my

left is Dr. Per Henriksen, who is Head of the Division for Chemical Food Safety, Animal Welfare and Veterinary Medicinal Products from the Danish Veterinary and Food Administration. And then we have Dr. James R. Johnson, Director of Infectious Disease Fellowship Program and Professor of Medicine at the University of Minnesota; Dr. Gail R. Hansen, who is Senior Officer for the Human Health and Industrial Farming Group of the Pew Charitable Trust; Dr. Christine Hoang, who is Assistant Director, Scientific Activities Division for the American Veterinary Medical Association; Dr. Randall Singer, Associate Professor of Epidemiology, Department of Veterinary and Biomedical Sciences, also from the University of Minnesota; Dr. Richard Carnevale, Vice President, Regulatory, Scientific and International Affairs from the Animal Health Institute; and Dr. Stuart Levy, who is Professor of Molecular and Microbiology and Professor of Medicine at Tufts University.

As you know, we ask each of you to limit your comments to 5 minutes, and then of course you can submit additional written comments as well, and we will start with Dr. Henriksen.

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^STATEMENTS OF PER HENRIKSEN, D.V.M., PH.D., HEAD OF DIVISION, DIVISION FOR CHEMICAL FOOD SAFETY, ANIMAL WELFARE AND VETERINARY MEDICINAL PRODUCTS, DANISH VETERINARY AND FOOD ADMINISTRATION; JAMES R. JOHNSON, M.D., F.I.D.S.A., F.A.C.P., PROFESSOR OF MEDICINE, UNIVERSITY OF MINNESOTA, AND FELLOW, INFECTIOUS DISEASES SOCIETY OF AMERICA; GAIL R. HANSEN, D.V.M., M.P.H., SENIOR OFFICER, HUMAN HEALTH AND INDUSTRIAL FARMING GROUP, PEW CHARITABLE TRUSTS; CHRISTINE HOANG, D.V.M., M.P.H., C.P.H., ASSISTANT DIRECTOR, SCIENTIFIC ACTIVITIES DIVISION, AMERICAN VETERINARY MEDICAL ASSOCIATION; RANDALL SINGER, D.V.M., M.P.V.M., PH.D., ASSOCIATE PROFESSOR OF EPIDEMIOLOGY, DEPARTMENT OF VETERINARY AND BIOMEDICAL SCIENCES, COLLEGE OF VETERINARY MEDICINE, DIVISION OF EPIDEMIOLOGY, SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF MINNESOTA; RICHARD CARNEVALE, D.V.M., VICE PRESIDENT, REGULATORY, SCIENTIFIC AND INTERNATIONAL AFFAIRS, ANIMAL HEALTH INSTITUTE; AND STUART LEVY, M.D., PROFESSOR OF MOLECULAR AND BIOLOGY, PROFESSOR OF MEDICINE, TUFTS UNIVERSITY

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^STATEMENT OF PER HENRIKSEN

} Dr. {Henriksen.} Thank you, Mr. Chairman, Mr. Ranking

Member and members of the subcommittee for inviting me to testify. First I can say I am a veterinarian by training, got my degrees from Royal Veterinary and Agriculture University of Copenhagen, Denmark. I have been working as a scientist for more than 10 years. I have been working in the farmers' organization as a health consultant for more than 5 years and working for the Danish government for more than 10 years.

As a representative of the Danish government, I am aware that the use of antibiotic growth promoters is a contentious issue in the United States and that Denmark is often mentioned in the debate. Against this background, I wish to emphasize that the Danish government is not represented here today to advocate for or against any specific legislative proposals. However, we are a nation willing to share our experiences when requested and therefore we have accepted your kind invitation.

I submitted five fact sheets for the record, and with the subcommittee's indulgence, I will therefore shorten my remarks to allow for your questions.

Mr. {Pallone.} I want to interrupt and say that I understand you obviously came from Denmark here today to participate in this hearing, and we really appreciate your coming so far to be with us today. Thank you.

Dr. {Henriksen.} Thank you.

Denmark is a major livestock producer in Europe and the world's largest exporter of pork. Danish livestock production is highly industrialized, intensive and supplies modern management principles. Due to the significance for the Danish economy, the Danish government takes the competitiveness of the Danish farmers seriously.

Treatment with antibiotics is in many cases essential for human and animal health and an uncritical use of antibiotics can lead to several antibiotics becoming ineffective. Because antimicrobial resistance can be transferred between bacteria, regardless of whether the bacteria are pathogenic or not, the development of antimicrobial resistance in any kind of bacteria can constitute a problem.

It is a fact that antimicrobial resistance can be transferred from animals to humans by consumption of meat, and every year also Denmark experience human outbreaks caused by consumption of meat contaminated with resistant bacteria.

A ban on antimicrobial growth promoters was considered necessary for several reasons in Denmark. There was science-based evidence that the use of antibiotics in animal feed could create resistance in pathogenic bacteria to medically important antibiotics, and there was a real concern that

doctors would run out of options for treating life-threatening infections in humans. Given the fact that very recently, a Danish Ph.D. project concluded that production animals and meat might be a source of human E. coli urinary tract infections, the Danish ban seemed to be an example of due diligence.

Among the initiatives that are all mandated by the Danish government, I would like to mention the following: No prophylactic use of antimicrobials and mandatory low fixation of the veterinarians' profit from sales of medicine. This fixation of low profit was an initiative of the Danish Veterinary Medical Association. The critically important antibiotics call fluoroquinolones can only be used in Denmark if a laboratory test shows that no other antibiotics can be used. Treatment guidelines for swine and cattle veterinary practitioners have been issued by the government. Continuous monitoring and research in antimicrobial resistance in animals, humans and food. Monitoring of foodborne pathogens in Danish as well as imported meat. Antimicrobial resistance is one of the parameters used to determine whether a shipment of imported food is dangerous or not. Control and action plans to combat Salmonella bacteria in poultry and pork and Campylobacter in poultry are implemented. And the most recent development includes mandatory action plans in

swineherds above a certain threshold value for antibiotic use, the so called ``yellow card.''

It is important to note that, according to our experience, a ban on antibiotic growth promoters can immediately and dramatically reduce the amount of antibiotics used. In Denmark the decrease was 40 percent. Such a ban should not stand alone in the long run. This explains the fact that we have implemented this range of follow-up measures and we can expect also to have to take additional steps in the future.

The ban of growth promoters has resulted in a marked reduction in antimicrobial resistance as measured among several different bacterial species in food animals. The percentage of macrolide resistance in porcine Campylobacter has decreased from 80 percent before the ban to less than 20 percent in 2006. A similar reduction from more than 75 percent vancomycin resistance in enterococci isolated from broilers before the ban to less than 5 percent.

Additionally, Denmark has a markedly lower level of resistant bacteria in meat compared to meat imported from other EU member states. I can mention as an example, that the percentage of cephalosporin resistance in E. coli isolated from Danish broilers' meat is less than 5 percent, while more than 35 percent of E. coli isolated from broiler

meat from other EU member states reveals cephalosporin resistance. This marked difference in resistance can be ascribed to our ban of growth promoters and low usage of antimicrobials compared to other EU countries.

The Danish swine industry has been producing pigs without the use of growth promoters for many years now and has increased both the production and the productivity. The same picture applies in the broiler chicken and cattle industries. In the last few years, and particularly in 20009, we have noted an increase of usage of antimicrobials above the concurrent increase in pig production. However, as this increase appears more than 10 years after the ban, we do not relate this to the ban. Nevertheless, we take this recent increase in usage seriously and have imposed several initiatives.

When presenting the Danish experience here in the United States, it is important to stress that Denmark is favored by a range of institutional characteristics which helped implementing the ban and the following steps. In Denmark, we can identify every herd, farmer and veterinarian and we are able to pinpoint the antimicrobial usage right down to the individual cow and to an age group of swine. This is due to our many databases on husbandry and medicine usage. And we have also monitored and researched in resistance for the past

15 years in a program called DANMAP. Our farming industry is highly organized in a cooperative structure with one common organization for farmers and food companies. We have a longstanding tradition for working towards a consensus between government, industry and the Danish Veterinary Medical Association. I would like to mention that the Danish Veterinary Medical Association along with the Danish Medical Association has supported a ban from the beginning.

Working as an entity, the Danish swine industry has therefore played an important role and voluntarily stopped all non-therapeutic use of antibiotics starting in 1998, with a total state ban in place by January 2000. Only 2 weeks ago the Danish swine industry again issued a voluntary ban, this time against therapeutic treatment with the critically important antibiotic cephalosporin. Danish farmers are well educated and have easily learned to produce pigs without growth promoters. Instead, they use good management, weaning at 28 days instead of 21 days, initiatives concerning food and proper care of sick animals. These institutional advantages have enabled Denmark to take ambitious risk-mitigating strategies in order to combat antimicrobial uses and resistance and without endangering the economic sustainability of the swine industry.

If you have any questions, I will gladly answer them, and I will also your attention to the fact sheet handed out. Thank you for your attention.

[The prepared statement of Dr. Henriksen follows:]

********** INSERTS 5, 6 **********

Mr. {Pallone.} Thank you, Dr. Henriksen.

Dr. Johnson.

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^STATEMENT OF JAMES R. JOHNSON

} Dr. {Johnson.} Chairman Pallone--

Mr. {Pallone.} Could you maybe bring that mic a little closer? I always gave Dr. Henriksen a lot of leeway, since he came from Denmark. The rest of you should try to stick to the 5 minutes. I think you have to either turn it on or move it closer.

Dr. {Johnson.} It was the turning it on. Thank you.

Chairman Pallone, Ranking Member Shimkus and members of the subcommittee, on behalf of the 9,000-plus members of the Infectious Diseases Society of America, or IDSA, I appreciate this opportunity to speak in support of the Health Subcommittee's efforts to promote judicious use of medically important antibiotics in animal agriculture. I am James Johnson, an infectious diseases physician, a Professor of Medicine at the University of Member, and a member of IDSA's antimicrobial resistance work group.

I applaud the emphasis that Ranking Member Shimkus and Congressman Pitts as well as other speakers today have put on science as a foundation and guide for decision-making in this area. I would point out that IDSA is made up of research scientists, infectious disease commissions and public health

epidemiologists who value and rely on the scientific method. IDSA supports rigorous science and critical impartial evaluation of the scientific evidence base. IDSA also publishes two of the premier peer-reviewed scientific medical journals in infectious diseases, Journal of Infectious Disease and Clinical Infectious Disease. These two journals have published dozens, if not hundreds, of peer-reviewed scientific studies on this topic.

IDSA supports efforts to eliminate all non-judicious uses of antibiotics in human medicine and agriculture such as the Preservation of Antibiotics for Medical Treatment Act, or PAMTA, and the FDA's recently announced public health approach toward antibiotic use in food animals. The elimination of non-judicious will mean the end of antibiotics for growth promotion, feed and efficiency and routine disease prevention in food animals. The United States also must strengthen efforts to ensure that all other food animal antibiotic use is supervised by a veterinarian within the boundaries of a valid veterinarian-client-patient relationship.

Now, IDSA regards the development of antibiotics to treat life-threatening infections as one of the most notable medical achievements of the past century. Unfortunately, these wonder drugs' ability to cure is being increasingly

compromised by emerging antibiotic-resistant pathogen, and there are few new antibiotics in development that will come to our rescue any time soon. As a result, infectious disease physicians and public health experts believe that we must do everything in our power to preserve existing antibiotics to protect both human and animal health.

As noted in opening statements by several committee member including Congressman Murphy and the Administration witnesses, an extensive body of scientific evidence demonstrates that antibiotic use in food animals does contribute to the spread of resistant bacteria to humans, leading to drug-resistant infections with their many adverse consequences. Our written testimony cites science-based studies and reports from authoritative panels over the past 40 years that support this position including studies supported by USDA and CDC. Eliminating non-judicious antibiotic uses in food animals would help protect the American people against drug-resistant infections and extend the utility of existing antibiotics. This concludes reflects a broad consensus within the medical, scientific and public health communities. Such measures have been advocated repeatedly by the World Health Organization and the National Academy of Sciences, and as you have heard here today, have already been implemented across Europe.

IDSA is very encouraged by FDA'S new draft guidance to industry which establishes a policy framework for judicious food animal antibiotic use. We view this new guidance as an important first step. Both FDA's guidance and PAMTA provide elements of the overall policy framework that Congress should consider as it moves forward to develop and enact legislation.

We are concerned, however, by FDA's apparent decision to rely on drug companies to voluntarily remove growth promotion and feed efficiency claims from their drugs' labels. Past experience suggests that this will take years or decades and many companies will not comply. Therefore, we urge Congress to expedite the process through legislation.

We also are concerned that FDA does not specify its plans for eliminating those uses of antibiotic in food animals for prevention, control and treatment that likewise may be non-judicious. These also must be addressed.

U.S. experts also require access to reliable and standardized data regarding the scope of antibiotic consumption in humans and animals. The lack of data in both the human health and agricultural settings impedes our ability to respond effectively to the antibiotic resistance problem. Although the U.S. Animal Drug User Fee Amendments, or ADUFA, legislation of 2008, as mentioned earlier,

strengthened FDA's ability to collect animal antibiotic sales and distribution data. This was only for national-level data. What we need are local-level data reported by animal species. Of importance, also pharmacists do not control antibiotic distribution in the agricultural sector. Instead, feed mill operators are responsible for mixing animals into antibiotic feed and they control antibiotic distribution from the drug manufacturers to our Nation's farmers. Given feed mills' key role in distributing these lifesaving drugs, they must become better integrated into the infrastructure for protecting antibiotic by tracing and regularly reporting to the FDA the amount of antibiotics being consumed by each animal species.

In conclusion, the Subcommittee on Health has a long history of leadership in addressing our Nation's most pressing public health issues. Today, IDSA calls upon you to help protect our patients and the health of every American by adopting strong measures including PAMTA to end non-judicious antibiotic use in food animals and to require that other food animal uses of these precious drugs be supervised by a veterinarian within a valid veterinarian-client-patient relationship. We also urge the committee to move with haste to enact the Strategies to Address Antimicrobial Resistance, or STAR Act, which will significantly strengthen U.S.

antibiotic resistance efforts. Finally, we urge you to enact statutory incentives to spur new antibiotic development.

Thank you, and I will be happy to answer questions.

[The prepared statement of Dr. Johnson follows:]

********** INSERT 7 **********

Mr. {Pallone.} Thank you, Dr. Johnson.

Dr. Hansen.

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^STATEMENT OF GAIL R. HANSEN

} Dr. {Hansen.} Chairman Pallone and Ranking Member Shimkus and members of the subcommittee, good afternoon, late afternoon, and thank you for inviting me. I am Gail Hansen. I am a veterinarian. I am a member of the AVMA, the American Veterinary Medical Association, and I also a Senior Officer with the Pew Charitable Trust.

Obviously, I care very deeply about this issue and I have worked on antimicrobial resistance from a lot of different angles. I was a State public health veterinarian for the Kansas Department of Health and Environment in Kansas, obviously, in working with both human and animal diseases. I was also a veterinarian in private practice for several years in Washington, New York City, North Carolina, and before I even got into veterinary school I was interested in this topic because I worked for the Food and Drug Administration, what was then the Bureau of Veterinary Medicine, in 1978. That was the year that FDA first proposed eliminating some drugs as growth promoters in animal feeds based on the science, and we are still here today.

I want to pick out one experience with a bacteria called Campylobacter that you have heard about to illustrate the

real problem of antibiotic resistance, and let me give you a quick background on Campylobacter. It is a real common foodborne disease similar to Salmonella and E. coli, which you may be familiar with. You get the same sort of symptoms. You have diarrhea, you have vomiting. It is pretty unpleasant. There can be some nasty complications that can occur with Campylobacter. I guess the good news about that is that we can treat it with antibiotic. The bad news is that the bacteria is becoming resistant to antibiotics. We also that this is a bacteria that is found in poultry and cattle. People get it from eating contaminated poultry or meat, as we have heard before.

So let me talk to you about the Campylobacter outbreak that I dealt with in Kansas in 1998 in Salina, Kansas. We had a middle school where we had over 100 people that got sick with Campylobacter. The physicians were using Cipro and tetracycline to treat people because those are the drugs that all the books said you should use, but then we found out that Campylobacter, that Campylobacter was resistant to both of those drugs so the physicians couldn't use those drugs. There was unequivocal evidence that the resistance came from antibiotic that were given to animals. Tetracycline was used and still is used in cattle and poultry, and at that time Cipro was used in poultry and it is still used in cattle

today.

So antibiotic resistance from feeding low levels of antibiotics to animals is real. It is here. We have got 40 years of science-based evidence and it is very clear. I have a book here which I have given you an annotated version of the bibliography of this that has some of the peer-reviewed studies that we have over the last 40 years, so there is plenty of science.

Antibiotics are overused in farm animals, in industry farming to the detriment of human health. Animals are fed low levels of antibiotics for growth promotion in the absence of disease, and especially when bacteria come in contact with low levels of antibiotics, it makes it much easier for them to become resistant to antibiotic. That whole thing of what doesn't kill you makes you stronger works for the bacteria as well. And then that resistance gets transferred to people and ultimately the antibiotics that we use for people don't work anymore for people and they don't work for animals either, and that is pretty scary.

But there are some effective alternatives to low-level antibiotic use available to farmers and ranchers. Just this last Saturday, I got back from a trip to Denmark looking at what Dr. Henriksen talked about, and how their industrial farmers are able to efficiently raise pork without the use of

non-therapeutic antibiotics. Farmers only give antibiotics, as he said, when they are prescribed by a veterinarian for a specific disease. The farmers at that point worked with veterinarians and with others to find effective management strategies that work.

So the American public really needs Congress to pass PAMTA. The FDA guidance document is not likely to fix the problem by itself. We need your help, and that is what PAMTA does. PAMTA disallows the use of seven classes of antibiotics that are critically important for human health to be used for non-therapeutic purposes unless it can be shown that the use doesn't contribute to antibiotic resistance in people. It still allows antibiotics to be used to treat sick animals. We absolutely have to have that. But we want to make sure that we protect antibiotics for people and animals. We can help the farmers and ranchers get past this outdated and very dangerous practice of feeding antibiotics to healthy animals.

Unfortunately, the American Veterinary Medical Association's position on PAMTA is different from mine and from many other veterinarians. I am disappointed, I guess is the best word, that the AVMA has not yet come to the same conclusions that the American Medical Association and the American Nurses Association, the American Academy of

Pediatrics has come to on the importance of this bill.

Thank you for the opportunity to testify. I would be happy to answer any questions.

[The prepared statement of Dr. Hansen follows:]

********** INSERT 8 **********

Ms. {Schakowsky.} [Presiding] Thank you.

Dr. Hoang.

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^STATEMENT OF CHRISTINE HOANG

} Dr. {Hoang.} Thank you for the opportunity to speak about antimicrobial resistance and the use of antimicrobials in animal agriculture. My name is Dr. Christine Hoang and I represent the American Veterinary Medical Association.

As a veterinarian with a dual degree in veterinary medicine and public health, and additionally certified in public health, my work is largely focused on scientific evaluations to inform the decision-making process both domestically and abroad through the AVMA, the Codex Alimentarius Commission and prior to that the Food and Agricultural Organization of the United Nations.

The AVMA's 80,000 members are engaged in every aspect of veterinary medicine and public health. As veterinarians, our oath ethically charges us with promoting public health and protecting animal health and welfare. With that also comes the responsibility to be cognizant of the potential health impacts in humans that may occur as a result of any decision that we make. The veterinarian must always the consider individual animal, other animals and humans in contact with that animal, and if it is a food animal, we must ultimately consider the people who consume the end product. The

decisions of the veterinarian go far beyond a single animal or person and an entire herd or flock and potentially hundreds of thousands of people that are affected by the many foods that are produced by a single animal. Therefore, as veterinarians, we carry a heavy burden but we do willingly with the knowledge, education and ability to make the right decision and to use the tools that are available to us appropriately and judiciously. Our members share the same concerns as our human health counterparts but yet we have additional concerns that must be considered: impacts on animal health and welfare and even negative impacts on human health that are often unrealized.

Two decades ago, a study concluded that human health hazards from growth-promoting uses could not be proven nor disproven. The debate continues today for that very same reason. A direct epidemiologic investigation still cannot be completed. Furthermore, there are divergent opinions due to differing levels of acceptable risk. For example, a person might find risk associate with food unacceptable, any risk would be unacceptable, but risks associated with high-speed driving perfectly permissible.

As veterinarians, we must consider many risks, risk to the animal, risk to ourselves, risk to our clients, risk to public health, risk of action and risk of inaction, and the

accepting of some of those risks in order to minimize others. Whenever antibiotics are used, there is some risk of resistance developing. That risk resistance can be transmitted to humans yet systems are in place that can trigger further investigation to determine the level of those associated risks. Risk analyses that evaluate only risk report adverse effects ranging anywhere from one in 32,000 to seven in 100 million. Risk analyses that also consider benefits indicate an increase in thousands of sensitive strained human cases for a reduction of a fraction of a single resistant case. Therefore, the greater risk of foodborne illness must be weighed against the many other factors.

We caution against preemptive bans based on the following observations in other countries: significant increases in therapeutic use as a substitution for growth promoters. The need for increased therapeutic uses are indicative of a decline in animal health and welfare associated with disease and no clear evidence of a significant human health benefit. Veterinarians are trained medical professionals with the ability to predict disease conditions and recommend appropriate therapy. Those uses should not be considered injudicious nor banned as routine use. If a disease is predictable and can be prevented, it is

incumbent upon the veterinarian to initiate appropriate therapy to prevent animal pain and suffering. Although over-the-counter antibiotic are available for such therapies, they are not unregulated. If a drug is not used according to the approved label indications for the dose, duration, disease or species or within extra-label drug use regulations, it is illegal.

The AVMA's antimicrobial use task force recently concluded that veterinarians should be involved in the decision-making process for the use of all antimicrobials in animals regardless of the distribution channel through which it was obtained. This would encompass prescription products, veterinary feed directives and over-the-counter antibiotics. Without exception, the AVMA is supportive of measures to mitigate risk to human health. To avoid potential diversion of resources away from more appropriate disease control measures, we encourage a regulatory strategy that is based on science, risk and benefit analysis, risk management that is commensurate with the level of risk, and cooperation with all relevant stakeholders. The AVMA is committed to providing consumers with the safest food possible and to protect human health against the current risk without compromising the health of food animals.

Thank you for the opportunity to appear before you

today.

[The prepared statement of Dr. Hoang follows:]

********** INSERT 9 **********

Ms. {Schakowsky.} Thank you, Dr. Hoang.

Dr. Singer.

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^STATEMENT OF RANDALL SINGER

} Dr. {Singer.} Mr. Chairman and members of the subcommittee, I would like to thank you for giving me the opportunity to discuss the role of antibiotics in animal agriculture. My name is Dr. Randall Singer. I am an Associate Professor or epidemiology at the University of Minnesota, both in the College of Veterinary Medicine and in the School of Public Health.

Antibiotic resistance continues to be a critical issue that affects human health, animal health and environmental health. All uses of antibiotics have the potential to select for resistant bacteria. What we are discussing here today, though, is risk and specifically the potential that the use of antibiotics in animal agriculture might result in more antibiotic-resistant bacteria that then lead to increased human health harm.

One of the antibiotic uses that is of particular concern is the approved label claim of growth promotion. The fact is that this label claim is almost 50 years old. It is an unfortunate label whose name has never been changed. Unfortunate why? Because we now know that the reason these antibiotics help animals grow faster is because these

antibiotics help animals maintain their health status. They prevent disease as well. And for evidence of this, we need to look no further than the Danish experience. It is a fact that following the removal of growth-promoting antibiotics in Denmark, the animals got sicker. Animal diseases that had been kept under control now appeared as a quote from their papers, epidemics, as stated by the Danish themselves. The unfortunate truth is that more than 15,000 swine producers in Denmark, over 60 percent of the total that existed before the ban, went out of business, most of these being the small and mid-sized farms.

But let us not focus on productivity. When it comes to antibiotics, we should be thinking about impacts on health. The only documented health benefit of the ban in Denmark was a decrease in some resistance in some bacteria on farms and in the community. There was no real human health benefit related to fewer resistant infections, at least that I have seen reported from the Danish experience.

Regardless, perhaps it is time to retire the outdated label claim of growth promotion. After all, its name implies a strictly production use of antibiotic. But let me ask you this. Since when it has become better to treat the sick than to prevent the disease in the first place? If we can give a lower does of a second-tier antibiotic to animals to prevent

a disease from occurring by, for instance, improving the gut health of that animal, isn't this better than having to treat an entire population of sick animals with a high does of a critically important antibiotic? The growth promotion doses give us that option.

We need to take a holistic view of health that seeks to maintain the healthiest animal population possible. Healthier animals lead directly to a safer food supply. Nobody in the animal industry wants to continue, though, with the status quo. Changes in production are happening. Companies are voluntary reducing their uses of antibiotics. But we still need options for preventing and treating disease and these are disappearing as can be seen in the poultry industry. The only animal agricultural antibiotic banned from use in the United States remains the fluoroquinolones in poultry production. There is another antibiotic. It has no human counterpart and it still has not been approved for treating disease in poultry in the United States. Both of these antibiotics are available as treatment options in Europe. I will stress that again. Fluoroquinolones are available in Europe as a treatment option.

In the absence of efficacious treatment options, the poultry industry at least needs the option of using antibiotics to prevent disease in the first place. What we

should be doing is determining what antibiotic uses minimize risks to human health while maximizing animal health. How do we begin to quantify those risks and determine the antibiotic uses that pose the least risk? FDA'S Center for Veterinary Medicine has an approved risk assessment approach as described in Guidance for Industry Document number 152. I was part of a team that used this approach to examine a specific antibiotic class, and we found that under the FDA's own definition, there was reasonable certainty of no harm to human health associated with this use. That is a peer-reviewed publication.

I am in full agreement with the many international reports and FDA statements that we need to continue to assess these risks but they need to be done a drug-by-drug basis in each animal species. All antibiotics that fall under the same usage category are not equal in terms of their impacts on resistance or their impacts on human and animal health.

In conclusion, Mr. Chairman and members of the subcommittee, I thank you for the opportunity to speak today. Antibiotics are an integral component of animal health and healthier animals lead to healthier people. I would hope that decisions regarding antibiotics, their approval and removal from use will continue to rest with the FDA's Center for Veterinary Medicine, who has in place a system for

assessing the risks to human health associated with animal antibiotic use. I hope that those who make the final decisions about antibiotic use are truly interested in all health, human, animal and environment, and agree that preventing disease is always preferable to having to treat the sick. The best way to manage antibiotic uses in animal agriculture is through sound, rational, science-based policy that evaluates the risks and benefits of all antibiotic uses. Thank you.

[The prepared statement of Dr. Singer follows:]

********** INSERT 10 **********

Ms. {Schakowsky.} Thank you.

Dr. Carnevale.

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^STATEMENT OF RICHARD CARNEVALE

} Dr. {Carnevale.} Chairman Pallone, Ms. Schakowsky and Ranking Member Shimkus and members of the subcommittee, thank you for the opportunity to appear before you today. I appeared before this committee some time back during the Animal Drug User Fee hearings, and I want to thank the committee for moving that piece of legislation through. We greatly appreciate it.

My name is Dr. Richard Carnevale. I am a veterinarian and Vice President at the Animal Health Institute. AHI is an industry trade association representing companies that make medicines for animals. Before AHI, I spent nearly 20 years at the FDA and USDA working on animal drugs and food supply.

While I submitted more thorough comments for the record, I would like to talk to you today about one simple truth: animals need medicines including antimicrobials. Without safe and effective medications to treat, control and prevent diseases, animal welfare would suffer and deaths would increase. Additionally, as Dr. Singer pointed out, healthy farm animals are critical to safe food. Animal health companies invest in the development of new medicines to provide veterinarians and producers the tools to keep food

animals healthy and must be able to rely on a predictable science-based regulatory process.

There has been much debate, as we all know, over the contribution of animal antimicrobial use to resistant bacterial infections in humans. Antimicrobial resistance is a serious public health threat but resistance is not a single problem. It is a problem comprised of several different bacteria/drug combinations that must be examined individually to ascertain risks. For example, some of the most widely recognized resistance problems in humans are in respiratory tract infections and venereal diseases like gonorrhea. In neither of these cases is there any evidence that antimicrobial use in animals is associated with these problems.

Both antimicrobial-resistant and susceptible bacteria can contaminate foods, our food safety system is comprised of multiple layers of protection to reduce their presence. The first layer of protection is a stringent regulatory review process at FDA. Animal antimicrobials must meet all the same requirements as antimicrobials used in humans with two additional requirements. First, sponsors must show that drug residues left in foods are safe for human consumption. Second, the FDA Guidance for Industry 152, which Dr. Sharfstein spoke of, outlines a qualitative risk assessment

process for new antimicrobials. This process is designed to estimate and manage the risk of antimicrobial-resistant bacteria that could be transferred from animals to humans.

Quantitative risk assessments have also been conducted and published on key antimicrobials, particularly those used in animal feed. A quantitative assessment is a more detailed review of each step along the food production continuum from farm to table that could contribute to or reduce the presence of foodborne bacteria. These studies have routinely reported extremely low levels of risk.

As Dr. Sharfstein discussed, FDA has announced two new initiatives relative to antibiotics used in food animals. These actions illustrate that the agency has broad authority to take actions it deems necessary to protect public health. AHI welcomes these initiatives and understands the reasons for their concerns. We will, of course, comment in detail to both publications.

A second layer of protection and one of the most important, in my opinion, is reducing bacterial contamination in slaughter and processing plants. Improved hygienic and pathogen-reduction measure in meat and poultry plants under the USDA HACCP pathogenic reduction regulation has significantly reduced bacterial contamination and therefore antimicrobial-resistant bacteria as well.

A third layer is in the multi-agency National Residue Program and National Antimicrobial Resistance Monitoring System to assure antimicrobials are being used properly and according to labels. Judicious-use guidelines which the AVMA representative has spoken about help to ensure that antimicrobials are being used responsibly in food and companion animals.

Finally, USDA has mandated safe food handling labels, and there are extensive food safety education programs that instruct consumers how to properly handle and cook foods to avoid foodborne illness.

Before I close, I want to note that Congress in the last 2 years passed legislation dealing with the use of antimicrobials in animals. The 2008 Farm Bill included a mandate for additional research on antibiotic resistance in food animals and the 2008 Animal Drug User Fee Amendments required FDA to collect antibiotic use data from sponsors by March of 2010. We expect the report from the agency later this year.

Mr. Chairman and members of the subcommittee, there are clear benefits to using antimicrobials to keep animals healthy including attending to animal welfare and assuring food safety. FDA has a stringent review process to ensure that antimicrobials are safe and effective. Monitoring data

from the NARMS program as well as public and private risk assessments have shown the process is working. With that said, FDA has recently articulated concerns with the way certain antibiotics are currently labeled and use. The animal health industry is committed to working collaboratively with the agency to address those issues while assuring that important animal health products continue to be available to prevent, control and treat animal disease.

Thank you for the opportunity to appear today and I welcome any questions.

[The prepared statement of Dr. Carnevale follows:]

********** INSERT 11 **********

Ms. {Schakowsky.} Thank you.

Dr. Levy.

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^STATEMENT OF STUART LEVY

} Dr. {Levy.} Thank you. Mr. Chairman and members of the subcommittee, thank you for inviting me to testify on this crucial subject of antibiotic use in animal husbandry. I am Stuart Levy, a physician, research scientist and Professor of Molecular Biology, Microbiology and of Medicine at Tufts University School of Medicine in Boston. I also serve as President of the Alliance for Prudent Use of Antibiotics.

For more than 3 decades, I have been studying antibiotic use in animal husbandry and its effect on bacteria associated with animals, farm workers and their families and the environment in general. Throughout my career, I have noted the paradoxical nature of human engagement with antibiotic, hence the title of my book, the Antibiotic Paradox. On one hand, antibiotics cure disease, are miraculous. On the other hand, they select among their targets those which are resistant and make these drugs not effective.

My own research stretching back to the early 1970s has confirmed the broad environmental impact of antibiotic use, and I stress that. We performed the first and only prospective study of the effect of introducing antibiotic-, in this case, tetracycline, laced feed for chickens on a

farm. By one week, almost all E. coli bacteria in the intestinal tracts of chickens were tetracycline resistant. By 3 months, the chickens and most of the farm dwellers were excreting E. coli not only resistant to tetracycline but to other antibiotics as well. We also demonstrated that low-does non-therapeutic amounts of tetracyclines can in fact propagate bacterial resistant to the drug and other antibiotics at high levels. Resistant bacteria were found to move among animals and from animals to people.

Antibiotics are unique. They are societal and ecological drugs. Each individual taking an antibiotic whether animal or person becomes a factory producing antibiotic-resistant bacteria. Thus, there is a difference in the environmental impact when the same amount of antibiotic is given to one as opposed to a number of animals sharing that particular environment. In principle, fewer animals will be given antibiotics and for less time when antibiotics are used prophylactically as compared to growth promotion.

Mr. Chairman, we are not gaining ground in the struggle against antibiotic resistance. Antibiotics are continually misused and overused in both human medicine and animal medicine at great cost to our society in terms of human health and cost of health care. It is estimated that

antibiotic resistance leads to more than $20 billion in hospital costs and up to $35 billion when society costs are included. Some progress has been made in encouraging more judicious use of antibiotics in human medicine but there has been precious little progress with respect to stemming the spigot of antibiotics flowing into animal agriculture.

In contrast, other industrialized nations have come to the same conclusion that many public health organizations around the world have, and that is that the use of antibiotics for growth promotion and feed efficiency must be curtailed. We can take some encouragement in the FDA's recent release of a draft guidance. We need to move with greater urgency to stem the use of antibiotics in industrial animal production. Because most antibiotics currently approved for growth promotion are also approved for routine disease prevention, I have great concern that feeding large quantities if antibiotics non-therapeutically will continue, rendering meaningless any FDA guidance on eliminating antibiotic use for growth promotion.

Mr. Chairman and committee members, in view of the certainty in my opinion of the public health threat, the history of regulatory inaction and unyielding nature of the relevant industry, it is now clear that even a well-intentioned FDA is unable to overcome the influence of

agribusiness. We have given moral assuasion, medical urgency, scientific study and voluntary guidance a chance and the situation has not changed. We can't wait any longer.

Legislation pending in this session of Congress, the Preservation of Antibiotics for Medical Treatment Act, would withdraw the use of seven classes of antibiotics vitally important in human health from food production unless animals are sick with disease or the use is needed for disease prevention without threat to human health. I urge this committee to move expeditiously to consider and approve this important legislation.

Thank you for giving me the opportunity to testify, and I will answer any questions.

[The prepared statement of Dr. Levy follows:]

********** INSERT 12 **********

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Ms. {Schakowsky.} I want to thank all of our witnesses. As is obvious, I guess, Mr. Pallone had to go to yet another committee that he is on where they are voting and so he won't be able to return.

I have some questions that I want to ask but I also want to let you know that we have a whole bunch of questions that I fear will not be asked and therefore we will get them to all of you and would appreciate very much your answers in writing later.

Mr. {Shimkus.} Madam Chairman, can we also ask, it wasn't done, I think, a UC that all members' statements can be submitted for the record?

Ms. {Schakowsky.} That all members' statements can be submitted for the record, without objection so ordered.

Mr. {Shimkus.} Thank you.

Ms. {Schakowsky.} I want to give a special thank you to Dr. Henriksen for coming from Denmark, and I wanted to give him the opportunity at this hearing to answer some questions, because there has been a lot of discussion about the Danish experience. We have seen articles and heard testimony claiming that even though you eliminated the use of antibiotics for growth promotion, you ended up using more antibiotic than you had before because all the animals got

sick. That is what we are hearing. And in fact, in the testimony of the American Veterinary Medicine Association, Dr. Hoang states and Dr. Singer as well that antibiotic use went up between 1998 and 2008. So can you clarify for us exactly what the situation has been with regard to antibiotic use in Denmark? And as part of that, can you tell us what steps you took to reduce antibiotic use and what the impact each step has had on the use of antibiotic?

Dr. {Henriksen.} Yes, I will try to answer your questions, all your questions. It is correct that after the ban the consumption of therapeutic antibiotics has been increased but in the same period the pig production has been increased too, and if you see my fact sheets on page 10, you can see figure 1 which both has the antibiotic usage in all types of animals and the number of pigs produced, and in that period from 1998 to 2008, you can see an increase in the therapeutic use of antibiotics but an almost similar increase in the number of pigs produced in Denmark. You can put it another way, that is to calculate how many milligrams per kilo pig produced in Denmark, and you can have the data before the ban. Before the ban in 1994, the total use of antibiotic growth promoters and for therapeutics were 99 milligrams per kilogram of pig produced, and even in 2008 the total consumption was 49 milligrams per kilogram pig

produced. That is, we have reduced the total usage of antibiotic per kilogram pig produced from 99 to 49 milligrams. That is a 50 percent reduction.

It is correct as stated by many U.S. observers that the disease situation has changed in Denmark. Diseases come and go in humans and animals, but if you look at the fact sheet on page 14, you can see the mortality in weaners, the mortality since 1993 to 2003, 2004 been increasing from about 2 percent to almost 5 percent, but since 2004 the mortality in weaners has decreased almost to the level from 1992-1993. So in that respect to mortality in weaners, the more focus of disease in Danish pig production cannot be released by the mortality figures. If you compare to the mortality in finishers in figure 7 on page 14, you can see that the mortality has been varying little during the 1992 to 1997, 1992 to 2007, but the mortality is between 3 and 4 percent. So there has not been any significant impacts on mortality neither in weaners nor in finishers.

I would like to add on the previous page on the fact sheet, page 13, figure 4, this is the productivity as we express it in Denmark, number of pigs produced per sow per year, and you can see from 1992 to 2006, 2007, the number of pigs per sow per year been increasing from 20 to more than 22 pigs per sow per year. That means that during this phasing

out of growth promoters has been increasing production, but I would of course admit in some farms you see severe disease problems, and this is the task for a trained veterinarian to deal with the specific problem in specific farms whether it should be a vaccination schedule, prophylactic changes in the environment, new ventilation system, better feed quality and so on, maybe prolonged weaning age from 3 weeks to 4 weeks, or treatment with antibiotic. So that I was think most of the question I think I answered.

Ms. {Schakowsky.} Let me just then underscore and make sure that this is correct, that the total antibiotic consumption in food-producing animals has been reduced by about 40 percent from the mid 1990s until today. So we are talking about total consumption is just almost in half or about 40 percent. Is that correct?

Dr. {Henriksen.} That is correct when you compare the total use of antibiotic growth promoters and therapeutic use in the end of 1997-98 to 2008, yes, that's correct.

Ms. {Schakowsky.} Thank you. I appreciate your being here and I appreciate your testimony.

Mr. Shimkus.

Mr. {Shimkus.} Thank you, Madam Chairman.

But I will say from ban until now, therapeutic use has gone up, and that--and you are shaking your head, which I

think that means yes. We do appreciate you coming a long way.

Madam Chairman, and this has been addressed with the staff for submission to the record a statement from the pork producer, if you would--

[The information follows:]

********** COMMITTEE INSERT **********

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Ms. {Schakowsky.} Without objection, so ordered.

Mr. {Shimkus.} Thank you, Madam Chairman.

The other thing I want to--I need to highlight some stuff going back to the previous panel and the third chart I didn't get a chance to talk about. I think the issue--I just want to get it on the record that the United States and Canada had pathogen reduction regulations during this time and the issues of voluntary withdrawal too. So there is more to be said by charts that unfortunately we didn't have time to pursue that with the previous panel because of time.

Another thing I want to make sure to put on the record, and this is from the D.C. area, that there is a huge price discrepancy between food products that are antibiotic-free and conventional price, and there is a list of 10 products here and it goes from anything from 141 percent to 20 percent change in retail prices. So another thing to place on the table is the cost of basic food products from beef to eggs to you name some of the issues.

Also, the reduction in Danish swine farms from the passage of legislation from 12,500 to 3,500, and for my friend from Denmark, the United States is the number 1 pork-producing country in the world. He knows that. I think is a percentage of what is exported based upon what is consumed.

But I would say second is the EU followed by, I don't know if it is Canada or Brazil, but this is a major industry in the United States. It is a major industry in my Congressional district, and that is why we want to make sure that science is addressed because we are concerned about antibiotic issues. We have had hearings. But we want to make sure that again that we don't do more harm than good. And I appreciate the various opinions and the issues on risk because healthy animals should grow bigger. I mean, if you are sick, you are not going to grow. If you are healthy, you do grow.

We just passed a health care bill that said preventative, let us make sure we keep Americans healthy because of the high cost in taking care of sick people, but here we are going to flip the charts. We are going to turn it upside down. We are going to say let us don't keep the animals healthy, let us do therapeutic antibiotics when they are sick.

Dr. Carnevale, I have two questions, because we heard from a lot of the panelists both here and then also on the first panel that there is unequivocal evidence, and it reminds me of the climate change debate, that the science is settled. Well, I think the American public understands that the science is not settled. Is there unequivocal evidence that there is a connection between the use of antibiotics in

animals and connect them to human health?

Dr. {Carnevale.} Well, as many have said today, this is a very complicated issue. I would say there is not unequivocal evidence that the use of antibiotics in animals, particularly those used in animal feed, are directly responsible for human health impacts, and human health impacts has been kind of loosely defined here, but I would certainly think that the most key human health impact would be failure of the treatment of a disease.

Mr. {Shimkus.} Yes, and let me--my time is very limited and I want to be respectful of my colleagues. And the animal feed issue is different than what the Danish experience was in the use of antibiotics. I don't want you to elaborate.

I want to follow up. My second question is, the FDA role. The FDA role is to make sure they approve drugs for animals and for humans. Now, when they say this antibiotic is good for use in animals, do they also look at its possible risk for human consumption through the process? Do they have to consider the effect on human health?

Dr. {Carnevale.} Yes.

Mr. {Shimkus.} So when the FDA says it is okay, it is not only saying it for the animal, it is saying it for human health and consumption?

Dr. {Carnevale.} Absolutely. They have a mandate to

approve drugs safe and effective, which means safe to the animal, safe to humans and safe to the environment.

Mr. {Shimkus.} My time is expired. Thank you, Madam Chairman.

Ms. {Schakowsky.} Thank you.

I wonder if you would mind if I just follow up with Dr. Henriksen, just find out what the Danish experience was on the cost of production after the ban. I don't know if--

Mr. {Shimkus.} No, we talked and I will be happy as long as our colleague down there is fine.

Ms. {Schakowsky.} Just a quick question. Was there any impact on the cost of production after the ban or the cost to the consumer after the ban?

Dr. {Henriksen.} The prices in the shop have not been increased due to this ban. I don't have any data available with me about the production costs for the farmer.

Ms. {Schakowsky.} Thank you.

Dr. {Henriksen.} I can present it to you if you want.

Ms. {Schakowsky.} Thank you.

Congresswoman Christensen.

Dr. {Christensen.} Thank you, Madam Chair, just a few questions.

Dr. Hoang, the AVMA, I understand, suggests that the current FDA approval process for antibiotic use in food

animals is sufficiently strict to protect human health but the FDA doesn't apply a standard regarding antibiotic resistance retroactively to drugs that were approved maybe decades ago. So what is the AVMA's position? Should we reevaluate the safety or not of already approved drugs?

Dr. {Hoang.} The AVMA is supportive of reevaluation of the drugs that have been previously approved, but I might also add that the FDA does have the authority to withdraw a drug if they find that there is an imminent human health hazard, which they have not done so.

Dr. {Christensen.} Thank you.

Dr. Levy, why do you think the United States has yet to follow the example of other industrialized nations in limiting antibiotic use in meat production? Is it because the scientific basis for action is questionable? It seems to me there is a lot of evidence. I don't think the bacteria behave much differently here than in Europe, so what do you think the reason is?

Dr. {Levy.} That is exactly what I was thinking. It has bothered me a lot as I go out to teach about how to use antibiotics that Europe, I think, is ahead of us by eliminating this major source of resistant emergence. Why? It is much more difficult in this country to get this ban. I had preferred all along in my career that it would be more

voluntary and that you wouldn't need a legislative ban, but I have been disappointed.

But anyway, all that being said, as we know, the Europeans looked at the data and with one fell swoop they said precautionary principle, we eliminate this use. I think the scientific data is clear, and I am a scientist and I have looked at the data, and the APUA has actually put out a few years ago an evaluation of this whole prospect with stakeholders and all agreed that this is no longer needed. First of all, we don't even know if growth promotion is really working. If it is prophylactic, let us call it prophylactic. And as I said in my statement, there is a big difference in terms of the selection of the numbers of animals that we get for growth promotion, which is everyone, whether healthy or not, versus prophylaxis, which in human medicine, look at what we do with surgery. We eliminated all that extra antibiotic and we gave a dose before and a dose or two after. Why aren't we doing that with animals? Where are the studies? If we call it prophylaxis, show me that it is prophylaxis. Show me what--I mean, a spade a spade. What is it? And so I think it is a different, should I say culture, but I don't think that anyone--there is plenty of us in the United States that agree with the European decision.

Dr. {Christensen.} And I noted Dr. Hansen in her

statement--I don't have a question for you but I know that you said that even in 1977, that is where I got the point I made in my opening statement, that the evidence was significant but we did not allow FDA to apply a ban. Is that correct?

Dr. {Hansen.} Yes, ma'am. I would certainly agree with that. I think that we certainly don't lack the science at all. We certainly have--this is just a representative portion of the science that we have. We may lack or we may have at least up until this point with all these hearings may have lacked some of the political will.

Dr. {Christensen.} Thank you.

Dr. Carnevale, how does AHI justify opposing significant reductions in antibiotic use in food animals when such overuse ultimately helps to contribute to the demise in your products' ability to treat both human and animal disease? Aren't you sacrificing long-term financial well-being, not to mention public health, in favor of short-term profit in this case?

Dr. {Carnevale.} If I understand the question, you are saying why do we oppose reducing antimicrobial use. I don't think AHI has ever said that. I think what our position is that these products have been approved as safe and effective by the FDA

Dr. {Christensen.} Safe and effective for treatment.

Dr. {Carnevale.} Safe and effective for all the claims on the label.

Dr. {Christensen.} From growth--

Dr. {Carnevale.} They have been approved as safe and effective for growth promotion, disease prevention, disease treatment and disease control, whatever is on the label.

Dr. {Christensen.} Well, FDA has issued some guidelines now regarding--

Dr. {Carnevale.} Yes.

Dr. {Christensen.} Does AHI support the guidelines that FDA--

Dr. {Carnevale.} We welcome the opportunity to work with the agency on their concerns about it. We clearly understand that they do have a concern about the way these products have been marketed for many years over the counter. We do understand they have a concern for the growth promotion claims. I don't want to prejudge the situation. I simply want to say that our companies are committed to working with the agency to try to address those concerns, and if there are alternatives that we can come up with for growth promotion claims, I am sure our companies will be more than happy to pursue that track.

Dr. {Christensen.} And are your companies--

Dr. {Carnevale.} Yes, we really want to work with the agency on this.

Dr. {Christensen.} Are your companies willing to report on the sale of medicines, drugs for animal use?

Dr. {Carnevale.} In fact, they are required to now under the Animal Drug User Fee Act. In fact, our companies have all submitted those reports to the FDA as of the end of March 2010. So yes.

Dr. {Christensen.} Thank you, Madam Chair.

Ms. {Schakowsky.} Well, that concludes all the questioning. I really thank you for your patience today, for staying with us all afternoon. In closing, I want to remind members that you may submit additional questions for the record to be answered by the relevant witnesses. The questions should be submitted to the committee clerk within the next 10 days. The clerk will notify your offices of the procedures.

And without objection, this meeting of the Subcommittee is adjourned. Thank you.

[Whereupon, at 5:55 p.m., the Subcommittee was adjourned.]