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RPTS STRICKLAND

DCMN SECKMAN

ANTIBIOTIC RESISTANCE AND THE THREAT TO PUBLIC HEALTH

WEDNESDAY, APRIL 28, 2010

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 3:50 p.m., in Room 2123, Rayburn House Office Building, Hon. Frank Pallone, Jr., [chairman of the subcommittee] presiding.

Present: Representatives Pallone, Dingell (ex officio), Green, Capps, Schakowsky, Matheson, Christensen, Castor, Space, Waxman (ex officio), Whitfield, Shimkus, Blunt, Pitts, Burgess, and Blackburn.

Staff Present: Ruth Katz, Chief Public Health Counsel; Sarah Despres, Counsel; Rachel Sher, Counsel; Elana Stair, Policy Advisor; Katie Campbell, Professional Staff Member; Stephen Cha,

Professional Staff Member; Virgil Miller, Professional Staff Member; Anne Morris, Professional Staff Member; Allison Corr, Special Assistant; Eric Flamm, FDA Detailee; Andre Bindman, Fellow; Clay Alspach, Minority Counsel, Health; Ryan Long, Minority Chief Counsel, Health; and Lyn Walker, Minority Coordinator, Admin/Human Resources.

Mr. Pallone. The hearing of the subcommittee is called to order.

Today we are having a hearing on antibiotic resistance and the threat to public health. And I will first recognize myself for an opening statement.

This is a very serious public health concern, and I know it is an issue of great interest to many Members of the House of Representatives. Antibiotics are among the most impactful medical innovations of the 20th century. When they were first discovered in the late 1920s, antibiotics became part of routine treatment to combat bacterial infections in the 1940s and were one of the main contributors in the decline of infectious diseases. Illnesses that had been widespread and often fatal prior to the development of antibiotics were suddenly curable with the administration of these new wonder drugs. In fact, the CDC lists control over infectious disease as one of their Top 10 Great Public Health Achievements of the last century and mentions antimicrobials as crucial to that accomplishment.

But bacteria, as we know, are living organisms, and as such, they can and will mutate with time to be able to resist the drugs that have been developed to combat them. And we now find ourselves in a situation where our triumph over infectious disease is in jeopardy.

More and more bacteria are proving to be resistant to the

antibiotics currently on the market. Unfortunately, these resistant diseases are among the most predominant illnesses in the population, including respiratory diseases, such as pneumonia; food-related diseases, including E. Coli and salmonella; and hospital-acquired infections such as Methicillin-Resistant Staphylococcus Aureus, more commonly known as MRSA. And I should point out that MRSA in particular is now migrating out of the health care setting and can also be found in the community posing a new threat to Americans.

Newspapers across the Nation report on the danger and prevalence of these bacteria. In my State of New Jersey, we had a number of schools close a few years ago after children were diagnosed with MRSA. Some were even hospitalized for weeks. And I am sure everyone here remembers the scare we had not long ago in the House of Representatives when MRSA was found in the House staff gym.

The consequences of these antibiotic-resistant bacteria are dangerous, expensive, and at times deadly. In 2005, the CDC estimated that roughly 94,000 Americans contracted MRSA, and over 18,000 died as a result of that disease, including young and otherwise healthy patients.

And many in the medical community believe that MRSA might not be as big of a threat as some of the other antibiotic-resistant diseases, as fortunately there still are some drugs that can treat MRSA.

For other diseases, like Acinetobacter, there are very few options. As articles in the press have highlighted, Acinetobacter was of particular concern among the wounded troops in Iraq: 35 percent of those infections responded to only one antibiotic on the market today, and 4 percent were resistant to all of our current drugs. It is pretty horrifying to me to think that our soldiers could survive a war only to then succumb to a bacterial infection we are powerless to treat.

In treating these highly resistant infections, physicians often have to prescribe more expensive, older, and less commonly used antibiotics that can cause serious side effects, including nerve and kidney damage. Patients end up hospitalized for longer periods of time and often suffer recurring infections that send them back to the doctor time and time again. And not surprisingly, these illnesses tend to be very expensive, not to mention the threat that they pose to all who come in contact with these patients, and that is why this hearing is important today.

I am very eager to hear from our witnesses about the problems we experience with antibiotic-resistant bacteria, but also about the work that they are doing to address these problems. And I know that both of your are engaged in some very exciting research that will hopefully help us attack antibiotic resistance in the most effective way possible.

I want to welcome you both to the committee. I apologize for the fact that we had to start so late. I know that one or both of

you mentioned catching a plane. I don't know what the situation is with that.

But for now, I will recognize our ranking member, Mr. Shimkus, for an opening statement.

[The prepared statement of Mr. Pallone follows:]

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Mr. Shimkus. Thank you, Mr. Chairman.

Antimicrobial drugs are a life-saving tool when used correctly. We know that microbes, including bacteria, can quickly evolve and become resistant to drugs, and resistance is already a concern in our communities, particularly in the hospital setting, where numerous deaths occur each year as a result of a resistance.

I am glad we have a panel before us from the CDC and NIH here today to discuss the role the Federal Government has played, particularly with the U.S. Inter-Agency Task Force on Antibiotic Resistance. I look in order to the hearing more on the progress made and what we might expect from the task force's updated action plan expected to be released later this year.

I have always believed a crucial component in this fight is providing industry incentives and regulatory framework that encourages the development of more antimicrobial drugs. Many manufacturers have turned away from the R&D of new antimicrobials because of increase incentives to develop drugs in other therapeutic areas and the uncertainty of the marketplace.

As members of this committee, we should work hard to break down the barriers encouraging the marketplace incentives, like extended patent exclusivity for new antibiotics and new economic incentives, such as an R&D tax credit.

Unfortunately, I believe that the $27 billion tax on the drug industry in the health reform law will have a negative effect and

will only serve to stifle, not encourage more, development of antibiotic drugs. Perhaps that is not the case, but this is another example of why we must hold hearings on the new health reform law.

Last week I raised issues we already knew were problems: pre-existing conditions coverage for children; individuals who do not qualify for the new high-risk pools; families being forced into Medicaid; premiums going to rise on average of $2,100 for those in the individual market; and being able to drop coverage and avoid penalties after 3 months and 1 day.

And this week we already have new questions. The majority repeatedly said health care spending will decrease. The President even pledged to the American people costs would go down, not up, as a result of health reform.

Yet CMS released a report by actuary Richard Foster last week saying national health care expenditures will increase by $311 billion, making health care 21 percent of the GDP.

Should we believe the CMS actuary expert or the majority and their bill, now law? Are the $575.1 billion in cuts in Medicare unrealistic and unsustainable as the report claims? Will the cuts drive 15 percent of hospitals in the red and force them to close their doors? How would this jeopardize access to care for seniors? What does the hospital community say about this?

Are 50 percent are seniors really going to lose their Medicare Advantage plans? Can 14 million low-wage working

Americans have their employer insurance dropped, forcing them into Medicaid? How will the State Medicaid plans handle these new populations and costs?

These are the questions being raised and the real concerns and fears coming from the public. This committee and this Congress cannot just bury our heads in the sand and pretend these problems don't exist in this massive health reform law.

Chairman Pallone, I asked before and I hope we -- and Chairman Waxman is here -- I hope we have hearings on the implementation of this law and address some of these problems that we should start moving to fix before they actually become problems. And I have identified quite a few of them.

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

[The prepared statement of Mr. Shimkus follows:]

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Mr. Pallone. Thank you.

Chairman Waxman is recognized for an opening statement.

The Chairman. Thank you very much Mr. Chairman.

We need to debate the health care bill and review its implementation. But we ought to be able to chew gum and walk at the same time. Because it is not going to make much difference if you have health insurance or not if you are going to die from something that could have been prevented from an antibiotic.

And we are seeing more and more antibiotic resistance. The revolution of antibiotics starting with penicillin in 1927 has been a major accomplishment in the health care world and has led to many people surviving things that in the past might have cost them their lives. Before we had antibiotics, common skin infections could turn fatal; child birth could be a death sentence for both mother and baby; and superficial wounds could deteriorate rapidly, often resulting in amputation.

Antibiotics changed all of that, and with the discovery of these medicines, doctors could regularly treat infections and literally save lives. The modern age of medicine was launched.

Some 80 years later, this medical miracle is still saving lives, and without antibiotics, many of today's cancer protocols would be nearly impossible to use because the immune system, when it becomes compromised by the treatments, would quickly leave people to die from opportunistic infections without antibiotics.

So, in brief, we cannot do 21st century medicine without antibiotics, whether you like the provisions of the health care bill or not. We need to have antibiotics available, and shockingly, experts, which I understand is supposed to be the reason for this hearing, are telling us that we are on the precipice of losing the power of many of today's antibiotics. As a greater number of bacteria become more resistant to them for reasons that we will explore this afternoon, antibiotics in turn become less effective, making infections far more hazardous to health.

This is not an exaggeration or hyperbole or even the stuff of some hypothetical computer model. This is not propaganda, which we hear a lot about in these committee sessions when people are campaigning for the November election and not looking at the issues that we have to deal with. Too many Americans have already succumbed to our inability to treat infections, and the numbers are staggering.

Today we will learn about the impact of antibiotic resistance on human health from two of the Nation's leading experts on infectious diseases: Dr. Tom Frieden, director of the Centers for Disease Control and Prevention; and Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases at NIH.

As we do, I hope we can start to understand and appreciate the severity of the problem that we face and together work toward a public-private plan of attack. I don't know what we need to do.

Obviously, research. That is our default and most important answer to any problem like this. But it is going to take a strong multifaceted yet coordinated strategy to get the job done. I think we have to think about things that have not been on the agenda for a while because of the pressure from some of the special interests.

What is the impact of using antibiotics without a medical need when it is applied to large numbers of animals? Is this resulting in more drug-resistant antibiotics? What will it take to get the pharmaceutical companies to do more work in this area? I met with a group yesterday who told me they need this, they need that, and they need the other thing, but they don't want to work on the antibiotics because it is not profitable enough. Well, let's look at that problem.

Let's look at whatever it is going to take and keep our eye on the objective. We cannot afford to live in a world where antibiotics don't work anymore. And I think the numbers are just so staggering: 90,000 Americans die each year of deadly hospital-acquired infections, which are predominantly caused by antibiotic resistant bugs. Over 18,000 Americans, including healthy young people, die annually from Methicillin-Resistant Staphylococcus Aureus, known as MRSA. We have seen soldiers defeat deadly enemies in Iraq only to return home with an epidemic of deadly antibiotic-resistant Acinetobacter.

And we need more hearings so we can say these words

correctly, because these are infections that we want to stop with antibiotics.

Thank you very much, Mr. Chairman. I look forward to the testimony.

[The prepared statement of the Chairman follows:]

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Mr. Pallone. Thank you, Chairman Waxman.

The gentleman from Kentucky, Mr. Whitfield.

Mr. Whitfield. Mr. Chairman, thank you very much.

We look forward to this very important hearing and certainly appreciate our two witnesses being here today.

I would, however, like to reiterate the importance and necessity, in my view, of holding hearings regarding the implementation of this massive and far-reaching change to our health delivery system.

As Chairman Waxman noted about hospital infections, according to the Centers for Disease Control and Prevention, 2 million people acquire bacterial infections in hospitals each year. And of that, around 90,000 people die because of these infections. And according to the information given to me, 70 percent of the hospital-acquired infections are caused by bacteria that are resistant to at least one of the drugs most commonly used to treat them.

I also do believe that we must explore incentives and other options to encourage pharmaceutical companies to continue their research and coming up with new medicines to deal with this problem. I look forward to the testimony of our witnesses today, and yield back the balance of my time.

[The prepared statement of Mr. Whitfield follows:]

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Mr. Pallone. Thank you.

The gentlewoman from the Virgin Islands, Mrs. Christensen.

Dr. Christensen. Thank you, Chairman Pallone.

And thank you, Dr. Fauci and Dr. Frieden, for being here, and it is good to see you again.

The hard facts and data about the prevalence of antimicrobial resistance are nothing short of astounding. Because of repeated and widespread improper antibiotic use, almost every type of bacteria has become stronger and less responsive to antibiotic treatment. Between 5 and 10 percent of all hospital patients -- that is roughly 2 million people -- will develop an infection, and 90,000 of these patients die. This trend is related to the fact that more than 70 percent of bacteria that cause these infections are resistant to at least one of the antibiotics that is most commonly used to treat them.

Though the full economic impact is difficult to determine, the estimated costs are somewhere in the vicinity of $5 billion a year. What is so disturbing is that because of this resistance, we are facing the prospect of reverting to times in health care where we are only able to offer a hand to hold. Not only may antibiotics be priced out of reach, but we may see cases where there are none that are effective in a given infection, and that is unacceptable.

As a physician, I know the pressures that we are always under

to prescribe antibiotics. I made it a point not to use them unless I thought they were indicated, either for my patients or my family. And I thank GW and Howard for that.

As I see it, the resistance horse is out of the barn. The only way to contain it is to fence it in by the National Institute developing the vaccines, as they did with Pneumococcus, which had as one of its goals the spurring the development of new antibiotics, and by the CDC campaigns that are directed at providers, including hospitals and the public, especially including the public.

None are easy but have to become a priority because this country and the world cannot revert to the dark days of medicine.

Thank you, Chairman Pallone and Ranking Member Shimkus, for holding this hearing.

Dr. Fauci and Dr. Frieden, I look forward to your testimony.

I yield back.

[The prepared statement of Dr. Christensen follows:]

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Mr. Pallone. The gentleman from Pennsylvania, Mr. Pitts.

Mr. Pitts. Thank you, Mr. Chairman.

Antimicrobial drugs have saved countless lives over the last half century and enhanced the quality of life for many more people. Unfortunately, we are observing a growing amount of bacterial resistance to antibiotics, and many infectious disease are becoming increasingly difficult to treat as a result.

There are multiple reasons for microbes becoming drug-resistant, including inappropriate use by physicians, inadequate diagnostics, hospital use, and agricultural use. I was pleased to see that in the majority's memo for this hearing they noted that, "The National Institute of Allergy and Infectious Diseases acknowledges there is debate about the public health impact," of antimicrobial use in animal agriculture, particularly in animal feed.

Because I believe that the legitimate and the judicious use of antibiotics in animal agriculture has been unfairly attacked and demonized in recent years. FDA puts these drugs through a rigorous approval process with many newer antibiotics having been extensively reviewed specifically to assess any risk to humans as a result of drug resistance. Treatment, prevention, control and growth promotion, feed efficiency are all FDA-approved uses for antibiotics. FDA also conducts post-approval monitoring, and multiple public and private surveillance systems monitor for any

sign of antibiotic resistance.

While every possible cause of antibiotic resistance should be studied and explored, I would hope that this series of hearings would focus more on areas where the science has told us there is cause for concern, and that is not the antibiotic use in animals.

I look forward to hearing from our witnesses, and I thank you, Mr. Chairman, for scheduling this hearing.

[The prepared statement of Mr. Pitts follows:]

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

Mr. Pallone. Thank you.

Chairman Dingell?

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

I have a splendid statement. I know that everybody will benefit by reading it. I ask unanimous consent to insert it into the record.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Dingell follows:]

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Mr. Pallone. Without objection, so ordered.

The gentleman from Texas, Mr. Burgess.

Dr. Burgess. Thank you, Mr. Chairman.

And due to the high-octane witnesses we have, I am going to waive an opening statement and submit for the record and reserve time for questions.

[The prepared statement of Dr. Burgess follows:]

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Mr. Pallone. Without objection, so ordered.

Did you have a statement? Oh, submit it for the record.

Let me just say all statements will be submitted for the record. Thank you.

The gentlewoman from Illinois, Ms. Schakowsky.

Ms. Schakowsky. I will put my full statement in the record, but I do have a couple of comments.

In my home State, the Illinois Department of Health has stated that in just 4 years, the incidence of MRSA has increased 57 percent to over 10,000 cases. As we are going to hear from the CDC and the National Institutes of Allergy and Infectious Diseases, antibiotics become less effective as humans are increasingly and often unnecessarily exposed to them. This can happen when they are overprescribed.

But it also happens through other types of exposure. It is for this reason I find the rampant use of antibiotics for nontherapeutic purposes in livestock populations alarming. Many factory farms give cows, chickens, and pigs antibiotics in their daily feed. They are not treating any known diseases. They are promoting growth and compensating for bad sanitation. When antibiotics are used in livestock populations, it gets into our food systems and into our water supply. Using highly potent medications for this type of use continues to contribute to the increasing prevalence of antibiotic-resistant infections.

I applaud by good friend, Representative Louise Slaughter, for introducing, The Preservation of Antibiotics for Medical Treatment Act, which would take needed steps to protect the effectiveness of antibiotics. I am a cosponsor of this legislation.

And I look forward to Dr. Frieden's and Dr. Fauci's testimony on this issue.

I hope you will address this as well.

And I yield back. Thank you.

[The prepared statement of Ms. Schakowsky follows:]

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Mr. Pallone. Thank you.

The gentlewoman from Tennessee, Mrs. Blackburn.

Mrs. Blackburn. Thank you, Mr. Chairman.

And Dr. Frieden and Dr. Fauci, thank you for being with us today.

I will have to say that this is a hearing that I have waited a long time for us to have.

I first wrote you, Mr. Chairman, in October 2007 with my concerns about MRSA and the fact that we needed to look into this. I find it astounding, when you look the at 2005 stats, that there are more people that die from MRSA-caused infections than those that die from AIDS, Parkinson's, emphysema, or homicide each year. And I do think that this is something that has to be addressed.

I was surprised, as I looked at the issue first in 2007, to find out from our Tennessee Department of Health that there is not a national standard on a way to report MRSA issues. And that is of concern to me. It is something that I want to address with both of you as we move through the hearing.

I do have a full statement that I want to submit for the record, but I thank you for the hearing and look forward to our witnesses.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. Pallone. And the full statement will be entered into the record. Thank you.

Our vice chair Ms. Capps, the gentlewoman from California.

Mrs. Capps. Thank you, Mr. Chairman, I will be very brief.

But I thank you for holding the hearing and thank our witnesses for coming today and for their testimony.

I have to give a special thanks to Dr. Fauci, who gave a stirring commencement speech for someone named Amy Fisher, who is now my medical health specialist on my staff. So you must have said just the right things when she graduated from Emory. Thank you very much.

This issue of antibiotic resistance is of extreme importance to both the health and the economic well-being of all Americans. Resistant strains of bacteria are harder to treat, often requiring longer and more difficult courses of treatment. And the longer an individual must spend fighting an illness, the greater the loss of valuable time at work and at home with families.

But there is also an economic consequence to the Nation as a whole. These infections cost the health care system, through extended hospital stays, more expensive treatments, nearly $5 billion in annual costs associated with hospital-acquired infections.

For many years, we have taken for granted that when we are sick, we can go to our doctor, take a week's worth of medicine,

and be well again. But now we must face the fact that we need a more comprehensive approach to treating bacterial infection. Perhaps more concerning is that there are a broad range of potential causes for the antibiotic resistance that affects us today: Individual factors, like when and what medicines a doctor prescribes and how well a patient adheres to treatment, combined with health-care-associated infections, agricultural antibiotic use, and a lack of new antibiotic treatments, all of these have contributed to the current state of antibiotic resistance.

I look forward to our witnesses' thoughts on how to employ evidence-based strategies to combat antibiotic resistance and the multiple factors that contribute to it in a coordinated approach. Thank you for being here, and I yield back.

[The prepared statement of Mrs. Capps follows:]

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

Mr. Pallone. Thank you.

Next, the gentleman from Utah, Mr. Matheson.

Mr. Matheson. Thank you, Mr. Chairman.

I have a full statement I will submit for the record, but I will make just one brief comment.

I just want to point out that on this important issue, I have once again reintroduced in this Congress H.R. 2400, the Strategies to Address Antimicrobial Resistance Act, or the STAAR Act. I believe this is a comprehensive piece of legislation to strengthen our country's response to pathogens that are increasingly becoming resistant to antibiotics.

Senators Sherrod Brown and Orrin Hatch will be introducing a companion bill in the Senate in the coming weeks. I encourage this hearing and others to move forward to, and I hope that piece of legislation, the STARR Act, can contribute to this debate and offer opportunities for us to make progress.

And with that, I yield back.

[The prepared statement of Mr. Matheson follows:]

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Mr. Pallone. Thank you.

The gentleman from Ohio, Mr. Space.

Mr. Space. Thank you, Mr. Chairman, for holding this hearing.

I would like to thank the witnesses for their attendance today.

I think we have all as a Nation kind of taken it for granted that antibiotics were there. And certainly, as a parent, I have not thought much about the consequences if they hadn't been there.

And it is a little unnerving now to see that, in combating some forms of bacteria, we can now say that antibiotics are less effective. In the words of Chairman Waxman, that this would be a very frightening world if it was a world without antibiotics, ring true.

I am pleased that the CDC and FDA and other agencies have begun to take some basic steps to combat the problem. I think public awareness is certainly a big part of it. I think this Congress and other agencies have an obligation to advance research into the issue.

My only hope is that if this Congress this term decides to take legislative action, that we do so with a sense of moderation, to the extent that that can be done. The concern always is that we may be overreaching. I certainly don't want to see that.

So researching and developing a solution to this problem is

very important, but ensuring access to antibiotics for all Americans is equally important during the process.

With that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Space follows:]

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Mr. Pallone. Thank you.

The gentlewoman from Florida, Ms. Castor.

Ms. Castor. Thank you, Mr. Chairman, for holding this afternoon's hearing on human resistance to antibiotic drugs.

Welcome to our witnesses.

This is a critical and rather frightening issue that we must work to resolve. Particularly the findings of the recently released Agency for Health Care Research and Quality Report are alarming. Post-operative blood infections increased by 8 percent. Catheter-related urinary tract infections increased by 3.6 percent. There are more statistics like that, and the numbers should be going down, not up.

I thought it was also disturbing that the report found that Blacks, Hispanics, Asians, and Native American patients were less likely than whites to receive preventative antibiotics before surgery in a timely manner. So we still have those disparities in health care. And all of these infections cause nearly 100,000 deaths each year and account for up to $26 billion a year in additional costs.

Many of theses infections are resistant to some of the strongest antibiotics, causing some patients to be in the hospital for weeks or months. In Florida, drug-resistant MRSA infections are growing and are infecting healthy adults and children. The number of cases in Florida from outpatient facilities increased

more than four times in the 3-year period from 2003 to 2005.

Drug-resistant gram-negative infections, different from MRSA, are also on the rise. These infections are primarily acquired in hospitals or long-term care settings. They have a high death rate and are resistant to antibiotics usually known as the last line of defense.

According to the CDC, the antimicrobial resistance problem is a major looming public health crisis. Researchers that I have heard from have highlighted to me the lack of resources coming from NIH for this particular issue. They have highlighted the lack of resources on the State level to detect, monitor, and control antimicrobial resistance in public health laboratories. Other States do not have the technical capability to detect and categorize resistance patterns quickly.

So, gentlemen, you have you your work cut out for you. We need your help in tackling this crisis. I look forward to your testimony.

Thank you, Mr. Chairman.

[The prepared statement of Ms. Castor follows:]

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Mr. Pallone. Thank you.

I think everyone has had a chance to give an opening statement, so we will now turn to our panel.

We have our two witnesses today. I want to welcome you. Let me introduce, on my left, Dr. Thomas R. Frieden, who is director of the Centers for Disease Control and Prevention; and to my right is Dr. Anthony S. Fauci, who is director of the National Institutes of Allergy and Infectious Diseases.

Thank you for being with us today. Sorry, again, you had to wait. You know that we have 5-minute opening statements that are made part of the record, and you can submit additional statements or comments after, and we may also follow up with some written questions.

STATEMENTS OF THOMAS FRIEDEN, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Pallone. So we will start with Dr. Frieden. Thank you.

STATEMENT OF THOMAS FRIEDEN, M.D., M.P.H.

Dr. Frieden. Thank you, Chairman Pallone, Chairman Emeritus Dingell, Ranking Member Shimkus and members of the subcommittee for your interest in this topic and for holding this hearing.

As an infectious disease physician myself and having worked as a tuberculosis control officer, health commissioner for more than 20 years I have seen the growing problem of drug resistance and also the potential to prevent and reverse drug resistance with effective public health action.

I appreciate the opportunity to speak with you today about the public health threat of antibiotic resistance and the role that CDC plays in preventing, detecting, better understanding, and responding to the problem.

I would like to share several slides to illustrate the problem. The first one shows the increase in drug resistance in two different organisms, Staphylococcus aureus, resistant to penicillin. Something that emerged almost immediately after penicillin became available. Early on, tiny doses of penicillin were able to cure severe infections with Staph aureus. Those resistant organisms first emerged in the hospital and then, after a gap of a decade or so, in the community.

That same pattern has existed with MRSA, Methicillin-Resistant Staph Aureus, which first emerged in

hospitals in the late 1970s, early 1980s, and over the past decade, we have seen increasingly in the community.

Antibiotic resistance is an increasing public health problem. Resistance occurs virtually wherever antibiotics are used. Many bacteria become resistant to more than one class or type of antibiotics, and doctors and nurses are now all too often faced with treating infections with antibiotic options that are limited or in some cases nonexistent. As resistance increases, both the risk of death and health care costs increase.

Addressing each antibiotic-resistant pathogen requires a balanced portfolio, a multifaceted approach that would reduce inappropriate use of antibiotics, prevent the spread of resistant organisms, and develop new antibiotics for the future.

Dr. Fauci will speak about the need to continue and accelerate our efforts to develop new antibiotics, but unless we improve our monitoring and use of antibiotics through effective public health action, we will steadily lose the ability to use both current and future drugs.

The next slide shows our approach to combating antimicrobial resistance. It starts with surveillance, understanding what is happening. Surveillance is key to assessing and monitoring the scope and magnitude and trends of antibiotic resistance. Surveillance data can drive and direct prevention efforts, and determine treatment recommendations, guide new drug developments, and evaluate whether our prevention efforts are working.

We need to detect and respond, including through more effective laboratory facilities in hospitals, in State and local health departments, and throughout the Federal system.

We need to develop and implement prevention strategies. An example of this: CDC working with the Veterans Administration hospital in Pittsburgh documented a 60 percent decline in MRSA infections. That same approach was rolled out to the VA system nationally and then to many other health systems nationally.

And although drug resistance is a growing problem, we have had some good news in that there has been a documented decline in MRSA nationally by about half and of Methicillin-susceptible infections in hospitals by about 70 percent, according to the hospitals that we track over time in the National Healthcare Safety Network.

And finally, to rigorously evaluate the impact to see what is working and what is not.

In my written statement, I highlighted several high-priority antibiotic infection and prevention strategies, and my next slide outlines some of those. MRSA, gram-negative rods, gonococcus, gonorrheal infections are becoming increasingly resistant in the U.S. and around the world; tuberculosis, where infections increase the risk of death and the cost of treatment.

Generally, we work to improve antibiotic use; facilitate rapid and accurate diagnosis; improve treatment of infections, and we have seen significant progress in reducing inappropriate

antibiotic use among pediatricians; improve infection control; and wherever possible, create and distribute vaccines, for example, to prevent pneumococcal infections, a vaccine which has prevented about 10,000 deaths and saved more than $300 million in direct medical costs each year over the past decade.

We speak of the pre-antibiotic and antibiotic eras. But if we don't improve our response to the public health problem of antibiotic resistance, we may enter a post-antibiotic world, in which we will have few or no clinical interventions for some infections.

We are working closely with our colleagues across HHS on this important issue. We very much appreciate the committee's interest and welcome your questions.

[The prepared statement of Dr. Frieden follows:]

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Mr. Pallone. Thank you, Dr. Frieden.

Dr. Fauci.

STATEMENT OF ANTHONY S. FAUCI, M.D.

Dr. Fauci. Mr. Chairman, Ranking Member Shimkus, Mr. Dingell, members of the committee, thank you for calling this hearing, and thank you for giving me the opportunity to discuss with you for a couple of minutes here the role of the biomedical research endeavor in the comprehensive strategy to address antimicrobial resistance.

As shown on the slide on the screen, as pointed out so well by Dr. Frieden, the strategy to address antimicrobial resistance includes surveillance, infection control, and the promotion by various means of the rational use of antimicrobials.

An important component of that strategy is the biomedical research endeavor fundamentally to understand the mechanisms of resistance and to do the basic and clinical research to develop the countermeasures that are needed against microbial resistance.

On the next slide is a picture of a journal in which we have published the research agenda of the National Institute of Allergy and Infectious Diseases which has three major pillars to it: basic fundamental research, clinical research, and transnational research leading to product development.

On the next slide, I want to very briefly address the issue of basic research. Fundamental to the basic research approach is the study of the microbe itself. We have been enormously put at an advantage over the last decade by the striking, if not stunning, advances in the ability to sequence and annotate the genomes of microbes.

Just to give you an example, in 1996, when the first microbe, haemophilus influenzae, was sequenced, it took about year and about a million dollars. In the year 2000, you could sequence a bacteria for about $50,000, and it would take about 4 days. Today, you can sequence a bacteria for $1, and it takes just several hours.

So we have the capability right now to do sequencing, mass sequencing, of microbes as they evolve into their resistant form. This gives us the opportunity of what we are pursuing very aggressively in our research to determine the molecular mechanisms of resistance and use that to target both diagnostic vaccines but, importantly, the targets for new pipelines of antimicrobials.

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[4:30 p.m.]

Dr. Fauci. In addition, we study the host pathogen interaction, namely how the microbe, be it a virus or bacteria, interacts with the host and what the body's immune response is in the form of immunological response.

On the next slide, we also do clinical research activities. And as Dr. Frieden has pointed out, we focus on some of the problematic organisms, in this case obviously one that was mentioned several times already this afternoon, Methicillin-Resistant Staph Aureus. In addition, the escape organisms, which are also prone to resistance, are on our top priority.

What do we do with clinical trials? Besides testing new drugs, we determine under certain circumstances, is treat even needed, such as in some of the infections that turn out actually to be viral infections that for which the use of antibiotics might not be appropriate?

We also need to know how much antibiotics we should use and for how long. The appropriate duration of therapy for different types of infections has still not been fully worked out.

And importantly, we are looking for new uses for older off-patent drugs. Drugs that have fallen into disuse because of

the more modern antibiotics might actually be brought back if into the ball game to treat multiple drug-resistant microbes.

On the next slide, it is a scheme that goes from left to right. I think this is a very important slide that I would like to just spend a minute on, because it is the scheme of what happens when you develop products for antimicrobials, in this case those that are resistant. On the far left is what the NIH, NIAID in particular, does best and does more intensively, and that is the fundamental research to develop the concepts to ultimately, on the far righthand side of the slide, to develop countermeasures. These could be diagnostics which are critical in addressing microbial resistance because you want to know if you are dealing with a resistant microbe. The other is a vaccine, which some of you have mentioned, to prevent some of the infections in the first place, and finally the development of new antimicrobial drugs.

As you go from left to ride, industry plays more and more of a role. As we have seen, the incentive for industry to get involved in the development of new antimicrobials is not very great. And I heard several of you mention in your opening statements, we need to address some of the incentives that we might partner with them in getting them involved in a very important public health problem that they don't have as an economic incentive something that is really a great drive on their force to get involved. And this is something that we generally use when we deal with emerging microbes for which there really are

not any countermeasures. I believe this is something that we should address when we are dealing with addressing of older microbes that have developed resistance.

Finally, just to go back to my first slide, on the next slide, to reiterate that there are multiple strategies and multiple components of strategies to develop the issue of antimicrobial resistance. And in conclusion, I want to say that we will continue to pursue the biomedical research approach as an important part of that comprehensive strategy.

Thank you, Mr. Chairman, I will be happy to answer questions.

[The prepared statement of Dr. Fauci follows:]

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Mr. Pallone. Thank you, Doctor.

Now we will have questions, 5 minutes, or in some cases 8 for some people who waived their opening statements.

I will start with myself for 5 minutes. I guess I am really addressing this to both of you, because both of you agree that resistance occurs wherever antimicrobials are used, whether they be in the community, on the farm, or in health care. I don't have time to explore all of these, so I am going to concentrate on resistance in the community and hope that my colleagues will talk about farm use or use in other, in health care settings.

Let me focus on the community. You both describe ways in which antibiotics are prescribed in the community, and to be clear, when say use in the community, I mean outside of the hospital. Dr. Fauci's testimony describes the fact that physicians often prescribe antibiotics to patients who have viral infections, not bacterial infections, simply because patients have come to expect or even demand treatment with antibiotics, even when they can't help. So my question is, how concerned should we be about these practices? Or I guess to put a bluntly, are doctors using antibiotics inappropriately and too frequently, and if that is true, what can we do about it? Either one.

Dr. Frieden. Thank you very much. The Centers for Disease Control has a survey called the National Ambulatory Medical Care Survey, or NAMCS. This is one of our main instruments for

determining what doctors' practices are and allows us to check over time what happens in clinical encounters. It is one of the few systems we have that is nationwide and allows us to monitor the quality of health care.

In these surveys, we have seen an improvement in that there has been a smaller proportion of patients who come in with, for example, upper respiratory infections, who leave with antibiotics, which they shouldn't leave with.

It still remains too comon a practice. The challenge is educating physicians and then having a monitoring system in place to give feedback to clinicians.

One of the things that will greatly facilitate that work is the expansion of electronic health records where clinical decisions support systems can remind doctors that this isn't a good use of antibiotics or can track and give feedback on what the behavior of individual clinicians are. So we need to both have the monitoring; we need to intervene by educating better; and we need to put into the process of health care automatic ways of telling doctors or helping doctors to make the right decisions.

I don't know, Dr. Fauci.

Mr. Pallone. I have to say, it is hard for me to relate to these questions because I never want to go to the doctor, and when I go, I always try to avoid having them give me anything, but I know it is a common practice.

Go ahead, Dr. Fauci.

Dr. Fauci. Actually, I would agree completely with Dr. Frieden.

Also, it is an issue of getting better, sensitive point-of-care type of diagnostics, where you could really underscore and confirm, because sometimes, when it physician a talking to a family member and they say, you have got to put my child or my husband or whatever on antibiotics because I know they either have an infection or are going to get one, and if you could in the office show immediately that that personal doesn't have a bacterial infection, I think it would go a long way to convince the person that the decision the physician is making is the appropriate decision.

Mr. Pallone. Well, what is the Get Smart campaign that the CDC has been working on, Dr. Frieden? Do you want to talk about that? And I guess you haven't recommended that it continue in the budget, so do you want to say why, or what it is and why you are not recommending that we fund it again?

Dr. Frieden. The Get Smart campaign is an educational intervention that works with physicians to try to reduce unnecessary or injudicious use of antibiotics. We are faced with significant budget constraints. We are not able to continue or expand all the programs which we would like to continue or expend, and we are committed to maintaining and strengthening work to reduce antimicrobial resistance in every way that we can within our budgetary limitations.

Mr. Pallone. So it is not that, the reason you haven't recommended continuing it, it is not because it isn't a good thing. But just it is not that important compared to other priorities. Is that fair to say?

Dr. Frieden. We believe the program is effective, but we are not able to include it in the current budget request.

Mr. Pallone. So the answer is yes, right?

I want you to reflect that you said yes, not me.

The gentleman from Illinois, Mr. Shimkus.

Mr. Shimkus. Thank you, Mr. Chairman. I am trying to get my handles around this, I think, conjecture that is making the claim that antibiotic use in animals is translated in changing the resistance in humans, which in one of the testimony didn't -- just kind of said that casually. There are assumptions made on the other side. Is there any peer-reviewed CDC study that shows a direct correlation to support that assumption?

Dr. Frieden. It is clear that any antimicrobial use will result, virtually any antimicrobial use, will result in emergence, persistence and spread of antimicrobial-resistant organisms, so the use of antibiotics in farm animals will generate the development and spread and persistence of antimicrobial resistance among the farm animals.

Your question relates to whether there is evidence that that resistance has spread to humans. We do know there are many interconnections between human and animal health. There is

experience from the several countries in Europe where prescription of an antibiotic that is related to Vancomycin was shown to be associated with an increase in Vancomycin resistance among humans. That was experienced in the European Union countries. That antibiotic was banned in the European Union, and the resistance levels then declined.

There is no scientific doubt about the theoretical possibility of transfer of parts of viruses, transpose onto other ways that you could spread antibiotic resistance from animals to people. There also are many outbreaks of --

Mr. Shimkus. I only have a limited amount of time.

But the question is, do you have peer-reviewed scientific research that shows this connection? Do you, the CDC?

Dr. Frieden. So what I said is there is peer-reviewed research in Europe.

Mr. Shimkus. I am talking about in --

Dr. Frieden. In the United States, it has not been, to knowledge, documented as having occurred.

Mr. Shimkus. Thank you.

My point is this, and I use this across the board in this committee, that running on emotions is running on emotions; running on science and fact, peer-reviewed replication is critical if we are going to move public policy. And we don't seem to want to do that here in Washington.

Do you know the Danish study? Have you followed the Danish

example of banning antibiotic use in livestock?

Dr. Frieden. I am not familiar the specific study.

Mr. Shimkus. Well, what they did -- not study -- they actually did, they actually banned antibiotic use in livestock, and what they found is a couple of things: Antibiotic resistance, even though it was banned, increased in humans, issue one. Issue two was antibiotic use increased in the use of animals because it was then used therapeutically. So then the other question that has to be asked is, would we rather have in the livestock consumption industry antibiotic use for healthy animals, or would we rather be using antibiotic use treating sick animals that then eventually go in the food chain?

So these are all part of this debate, and I just want to caution people to make this jump on this without scientific research, peer-reviewed study that really makes a direct correlation, and I think, again, my friends would want to do this.

One of the issues of this is the industry; how do we get industry, in one of these charts, to develop that? And we have done that with different types of drugs. And Chairman Waxman has been very good PDUFA and stuff. How do you get industry to market in areas we want to do?

I will tell you one thing you don't do, you don't add an additional $27 billion tax to an industry you are trying to incentivize to create life-saving antibiotics, which we just did in health reform bill.

And I am concerned that if we go and take antibiotic use out of livestock, if you believe in economics 101, supply and demand, you reduce another supply avenue for selling antibiotics. Then you limit the ability of a return on investment on those companies that are producing it to begin with.

So this is an important hearing, and there are a lot of scientific aspects of this. But I would just plead that we make sure that any action we do is not based upon emotion, but we do peer-reviewed science.

With that, Mr. Chairman, I yield back my time.

Mr. Pallone. Thank you, Chairman Waxman.

The Chairman. I am trying to understand the science. It seems to me, from what I have understood, that when you use an antibiotic over and over and over again inappropriately -- by inappropriately I mean not to deal with the bacterial infection but for other reasons -- whether it is used on an animal or on people, it increases the chance of resistance to the antibiotic. Is that the correct statement of the science, whichever of you would like to say?

Dr. Fauci. Yes, it is. That is just the nature of how organisms are involved. You put any pressure on them, they will select for survival, and survival is resistance. It is just a natural phenomena of the interaction of a microbe with a pressure you put on the microbe. That is the scientific reality.

The Chairman. So to avoid antibacterial-resistant microbes,

we should be sure that we are using the antibiotics where it is necessary and not using it where it doesn't have a therapeutic purpose. Does that make sense?

Dr. Fauci. Correct.

The Chairman. You are both answering yes.

Dr. Frieden. There is no disagreement about the use of antibiotics to treat infections, nor is there disagreement about the theoretical risk of promotion of drug resistance through the widespread use of antibiotics.

The Chairman. Now, I don't know of anybody who would argue that we shouldn't give an antibiotic to an animal that has an infection, because it is for a legitimate therapeutic purpose. I haven't heard anybody argue that we shouldn't give an antibiotic to a person who has a bacterial infection if that antibiotic could stop that bacterial infection.

But if you give it to large numbers of animals for nontherapeutic purposes, let's say as a preventative, and if you give it to kids who may have a virus and not a bacterial infection, aren't we running a greater risk of resistance?

Dr. Frieden. Yes, our basic principle is to promote judicious use of antibiotics. The Institute of Medicine has called for the phasing out --

The Chairman. Is this from science from Europe, or is this science that is accepted here in the United States?

Dr. Frieden. Public health authorities, including the

Institute of Medicine, have called for phasing out of uses to promote growth. There is no disagreement, as you note, about use for treatment or evidence-based prevention of infections.

The Chairman. Now, Dr. Fauci, I think you particularly raised the question that we don't have companies making new products where we need new breakthroughs in antimicrobials. And it appears to be a market failure.

Now I don't accept the idea that if we used it in a more widespread way, that that would encourage the drug companies to make more antimicrobials. It sounds to me like we are running a risk of making more bacterial-resistant diseases. It might make them more money, but I am not even sure then, because the product won't work after a while.

We have had market failures in the past, and you and I were in this room many years ago when we first heard about the AIDS epidemic, and we are trying to deal with it. And there was a small patient population. We didn't know what resources we had to treat them. In this room, we had many hearings on people with rare diseases, and it didn't offer profit potential for a lot of the companies to put efforts into drugs for people with -- a small number of people, in effect, for diseases.

We came up with the Orphan Drug Act. We have tried to give other incentives for research and development. We have a patent law. We have removal of time that is lost at FDA to help the producers. Do you have any other ideas on how we can correct what

appears to be a market failure? Is it because it is just not profitable to produce these antimicrobials, because it is just too few seldom used and not widespread enough?

Dr. Fauci. Well, certainly, that is, Mr. Waxman, one of the major reasons why not. Pharmaceutical companies, who do great things, are driven by the profit margin and what they have to answer to, to their boards. And if a company has a choice in making a major investment, to develop a new product, a new drug, it is several hundreds of millions of dollars, an average of around $700 million, which includes a risk that they take in the development of the product. So if they are going to make a choice of making a product that a lot of people are going to take every day for the rest of their lives, a lipid-lowering agent or whatever you have, they are going to lean towards that rather than to make a new product that a relatively small proportion of the population will use maybe 10 days to 2 weeks out of the year and then, because it happens naturally, that after a period of time, there is going to be resistance against that antimicrobial.

So from the interactions that I have had with industry, we need to work with them in partnership to figure out what incentives that we can do. We at the NIH, I showed that slide, we fundamentally do basic and clinical research, but what we are doing now is offering some of our research resources, our animal model capabilities, our reagent repositories, and even our clinical trial capabilities to lessen the risk of an investment on

industry to give them more of an incentive to get involved. And I am sure there are other types of financial incentives that can be worked out in an appropriate way. But I really do think we need to push the envelop a bit in getting rid of some of disincentives for getting them involved.

The Chairman. Just one last question, Mr. Chairman.

I assume this was a problem even before the health insurance bill was passed last month?

Dr. Fauci. Yes, sir.

Mr. Shimkus. It is probably a bigger problem now though.

I yield back.

Mr. Pallone. Thank you, Chairman Waxman.

The gentleman from Texas, Mr. Burgess.

Dr. Burgess. I am struggling to keep from taking the bait.

Let me depart from what I was going to do for just a moment, because the whole issue of profitability -- penicillin, a truly wonderful discovery. Sir Alexander Fleming, appropriately knighted by the king or the queen, appropriately honored with a statue erected by the bull fighters in Spain, but really it was an American manufacturing company, I think it was Pfizer, in the Second World War, that changed penicillin from kind of a parlor trick that inhibited the bacterial growth on an agar plate to one of clinical utility for thousands and indeed hundreds of thousands of people because of the ability to create a lot of it in the manufacturing process that they developed in the Second World War.

You argue from purely a profit motive, they would have kept the numbers of doses of antibiotics low and kept the price high. But they went with the mass production, and as a consequence, soldiers during D-Day were spared life and limb because that they had readily available, abundant, cheap penicillin, which you alluded to on your slide worked well until that darn bacteria figured out that they could chew up that beta-lactam ring and survive quite nicely with their cell wall in tact in spite of the penicillin. So it is not always a profit motive.

I am telling you stuff that you know better than I. This was a seminal event in American medicine. It fundamentally changed the way all of them and subsequently all of us were trained and practiced in the generations that followed. I mean, it truly was a life-altering event.

But let's think for just a minute, Dr. Fauci, the new molecular entities for broad-spectrum antibiotics that have been introduced by the FDA in the last 10 years, do we have an idea of how many new drugs have been produced?

Dr. Fauci. Very few.

Dr. Burgess. Broad-spectrum antibiotics.

Dr. Fauci. New antibiotics, very few; I mean, handfuls.

Dr. Burgess. I have a list of 10. Does that sound right?

Dr. Fauci. That sounds about right.

Dr. Burgess. But I have got, my staff has gotten me about 25 pages of antibacterials that have been approved for new

indications, and you referenced that in your slide; new chores for old drugs that we might find. But these older drugs are not necessarily helping us fight the war against resistance; they are just an antibiotic that was found to have an indication for something else.

So the problem is, if there are only 2 -- I mean 10 truly new antibiotics produced in the last decade, and then another document that tracks $92 million in Federal research at your institute, Dr. Fauci, in fiscal year 2009 alone on antibiotics research -- does that sound like a fair figure?

Dr. Fauci. No, actually, on antimicrobials research, we do about $790 million of research; on resistance specifically, we do about 200-plus.

Dr. Burgess. Okay. So my numbers were low.

Dr. Fauci. Right.

Dr. Burgess. So taxpayers are pumping in a lot into the pipeline, and we are getting out at the other end approximately the average of one new antibiotic a year? Is that -- am I making a correct --

Dr. Fauci. Now --

Dr. Burgess. Well, I would just ask the question, do we have a problem with -- it sounds like we have a problem with the pipeline, so where in the pipeline is the problem? Is it the dollars we are pumping in? Is it the research we are putting into it? Is it the FDA? Where is the problem in the pipeline?

Dr. Fauci. Well, I think, Mr. Burgess, the problem in the pipeline is right in the middle of that arrow that I showed in one of my slides, and that is that the pharmaceutical companies, as much as we can do research, we can sequence now, as I mentioned -- I mentioned that for a reason. We can sequence a thousand microbes for a reasonable price really, really quickly. We can pinpoint all the different targets that could serve as a target for the development of a drug. There is not an overwhelming incentive on the part of companies to get involved in developing a new antimicrobial.

That is why, in answer to the question of Mr. Waxman, I emphasized that there are a lot of issues that go into why we don't have a lot more drugs for the amount of fundamental research money that we put in, but one that is really paramount is to get the companies involved and incentivized into wanting to make them. And I don't have the complete answer for that. We are trying the things that I mentioned in response to Mr. Waxman's question, but we need to do better than that.

Dr. Burgess. Yeah, I do not want to cut you off, because I know your position in the scientific world and mine, but I need to ask you this, so market incentives, are those always dollars? Or are there changes we can make at the regulatory level that would help the environment?

Dr. Fauci. The FDA right now is putting a considerable effort in pushing what is referred to now as regulatory science;

in other words, to get them involved in developing bioassays, biomarkers, new clinical trial designs that would facilitate the development of any product, including a product that is geared against a resistant microbe. So there is something we could do at the regulatory level, and the FDA is really trying very hard to push that agenda.

Dr. Burgess. Well, I am going to ask Mr. Shimkus this question, because I can't help myself. We put $27 billion new tax on to the industry under the health bill, so is that likely to have a positive or negative effect on the pipeline problem that we have?

Okay, we will go to the next question. Does your institute track how much of their research invested has translated into applications and approvals at the FDA? So what kind of data does the National Institute of Allergy and Infectious Diseases have that could be shared with this subcommittee?

Dr. Fauci. When you say information, everything we do is transparent. You can get any information that you want. But I think you were asking --

Dr. Burgess. The applications and approvals that then go over -- the applications that go over to the Food and Drug Administration, and the approval of those applications that come out at the other end.

Dr. Fauci. As a product?

Dr. Burgess. As a product.

Dr. Fauci. See, that is a question that is difficult if not impossible for me to answer because we don't control the concept to product. We do fundamental research that might develop the concept that can be pushed to the pre-clinical, but if we were solely responsible for soup to nuts, I could give you an exact answer.

Dr. Burgess. All right.

Dr. Fauci. But we are not. We have to punt it to the pharmaceutical companies. That is the point.

Dr. Burgess. But on the slide that one of you showed with the Methicillin-Resistant Staph Aureus and the numbers going up and now community-acquired. I think it is a huge problem in jails, and it is a huge problem in dormitories and homeless shelters. It seems like the market is being created, and none of the companies are interested in being the first one to cross the finish line with the silver bullet that wipes out MRSA? Where is the Paul Ehrlich of our generation?

Dr. Fauci. I would think, personally, that a company would be very interested in getting in it. They balance the risk for the benefit. And as I mentioned, there is a considerable risk for a company to put several hundreds of millions of dollars to develop a product. And what I would be proposing is that somehow we in the Federal Government help alleviate that risk by doing some of the things that I mentioned we can do, but we are not the only player in this.

Dr. Burgess. Let me just ask you a quick question on hospital-acquired infection. My epidemiologist that I rely upon a lot back in Dallas is Bob Haley, and he told me early on that in order to fix something, you have got to be able to measure it; in order to measure it, you have to drive out fear. You can't have people frightened to report data to you, or you will never have the accurate data to measure. Is that a valid observation?

Dr. Frieden. Yes. In fact, we have expanding reporting of hospital-associated infections. Already 28 States report mandatorily, and about half of all hospitals in the country.

Dr. Burgess. Just briefly, to the point, what is the best approach here? I have always felt that of the 28 States that report, you know, find the best practice or set some floor, perhaps at the Federal level. Let you guys deal with the de-identified and aggregate data so you are not getting into patients' privacy issues, so that you have the data to study, as opposed to what we seem to see here at this committee sometimes looks very, very punitive. I will just tell you, as someone who practiced medicine for years, if you make it punitive on the doctors, we will find a way to obscure things for you, so you don't pin it on us. I am over-simplifying, but really, that drive-out-fear concept is one I think we need to embrace, CMS needs to embrace, and I would encourage you to continue to work along that line. I think that is where the ultimate answer for this problem lies.

Thank you, Mr. Chairman, for your indulgence. I will yield back.

Mr. Pallone. Sure.

Chairman Dingell.

Mr. Dingell. Thank you, Mr. Chairman.

Gentlemen, welcome to the committee.

I am curious, has there ever been a definitive study on the impact on microbes and other similar creatures to define what the impact on them might be in terms of resistance to antibiotics by reason of using these antibiotics in animal feed and for other similar uses?

Dr. Frieden. There are clear studies that show that use of antibiotics in animal feed increases resistance among animals.

Mr. Dingell. Among animals or amongst bacteria?

Dr. Frieden. Resistance in the bacteria that resident within animals.

Mr. Dingell. Would such a study be useful? I mean, a thorough-going analysis of the matter as opposed to just bits and pieces.

Dr. Frieden. There is an increasing body of evidence that looks at where antibiotic resistance emerges and how it spreads. An additional evaluation of that to understand the spread from animals to community I think is something that many groups are working on. There is not right now definitive evidence. There is a clear understanding that the more judiciously we use

antibiotics, the longer we will be able to continue to use them effectively.

Mr. Dingell. Now has ever any work been done to define what is efficient use of antibiotics in animal feed? In other words, how much is necessary? How much is too much? How much doesn't work? How much we could do without, and what would be the benefits of the different steps? Has there been any study of this kind?

Dr. Frieden. As the director of the Centers for Disease Control and Prevention, I would have to defer to my colleagues at the FDA and USDA on those questions.

Mr. Dingell. Who else? I don't see the FDA here in the room. Who has authority to do this kind of research or to fix this level of tolerance or content or the time at which these antibiotics are fed or inserted into animal feed?

Dr. Fauci. Mr. Dingell, I would imagine that the most appropriate venue to do that would be through the U.S. Department of Agriculture.

I mean, that is an obvious question of great importance for people who --

Mr. Dingell. Do they have the authority to fix this or not?

Dr. Fauci. I don't know if I could answer that definitively. I cannot imagine that they don't have the authority to do a study if they would want to do it.

Mr. Dingell. I can imagine, A, that they don't have

authority and, B, that they don't use it if they do.

Now let me go into some other questions. CDC's overall budget would see a 5 percent cut, and the antimicrobial resistance program would receive a cut of more than 50 percent.

Gentlemen, do you think these cuts would negatively impact the work you are doing related to antibiotic resistance, especially support for State and local surveillance, prevention and control efforts and the Get Smart campaign?

Dr. Frieden. Mr. Dingell, we are committed to doing as much as we can.

Mr. Dingell. That is not an answer to my question. Is that level of cut going to hurt what you are doing?

Dr. Frieden. It will be difficult for us to continue current programs at that level.

Mr. Dingell. Would you tell us, would you submit for the record the level of your request for financial support for these programs in the budget? And also submit the amount that you have been given for the last 3 years and for the coming 3 years.

Dr. Frieden. We will provide that information.

Mr. Dingell. All right.

Now, you have addressed this slightly, but I would like a little more on it. There appears to be much debate over whether the practice of adding antibiotics to agricultural feed is sought to promote drug resistance. What does current science and surveillance tell us on this point? Is there a direct link, and

what is it?

Dr. Frieden. I think we know that theoretically there is a risk. The literature that we have reviewed outlines a problem that clearly emerged in Europe. I am not aware of evidence in this country that has documented the spread from animals to humans, feed animals to humans, we have of course seen spread from animal to humans in a wide variety of infections. But we know that the more antibiotics that are in the environment, given to animals and people, the higher the selective --

Mr. Dingell. Let me try, sir, to try to reduce this. I am getting the impression from what you two gentlemen are telling us here is that we really don't know what the nexus between the feed is and 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? What comment do you make on that statement?

Dr. Fauci. From your questions, Mr. Dingell, and the questions we have from the other members, there is no doubt in anyone's mind that if you give antibiotics to anybody, any animal, and you do it chronically, that resistance to microbes will evolve.

I think the question that Mr. Shimkus brought up and that others is that, what is the evidence that if you give it to an animal for feed and resistance develops in microbes in that animal, that that resistant microbe will then spread to a human? And I think --

Mr. Dingell. It might spread to other microbes, or it might spread to humans.

Dr. Fauci. Right.

Mr. Dingell. Rather than coming to the conclusion, you don't have much information on that account.

Let me get to this, because time is limited here. The Food and Drug Administration withdrew its approval for the use of fluoroquinolone antibiotics, that is FQs, in poultry. Are there any preliminary, any RMS surveillance reports that would indicate the impact of FDA's decision? Yes or no.

Well, would you --

Dr. Frieden. We would have to get back to you on that to give you the most recent information.

Mr. Dingell. Would you submit that for the record?

Dr. Frieden. Absolutely.

Mr. Dingell. Dr. Fauci, in addition to the work that your agency is currently engaged in with the smaller manufacturers, what additional steps can or should be taken to incentivize participation of industry, both large and small manufacturers, in developing new effective therapies for these drugs-resistant infections?

Dr. Fauci. There are several things that can be done, Mr. Dingell. One is to make available to the company some of the assets and capabilities that we have in the government, including in my own institute, and that is various assays, reagent

repositories, animal models and clinical trial capabilities; and then also to reach out and partner with them on the risk for the advanced development, something that that they generally do themselves. If we could diminish somewhat the risk they take, I think there will be much more of an incentive for them to get involved.

Mr. Dingell. Is this question raised at any point in the government regulatory structure when you address the questions of whether or not or how much antibiotics should be used in animal feed? And if so, who has authority to do that?

Dr. Fauci. Well, we certainly, that is not something that we as a research institution get involved in.

Mr. Dingell. Here is the purpose of for my question, if they are putting too much in the animal feed and not using it wisely and don't have any particular constraints on its use, we are obviously increasing a risk if a risk there is; is that right? Clearly, the answer to that is yes.

Dr. Fauci. Well, I am not sure what --

Mr. Dingell. Would you say there is no risk in this?

Dr. Frieden. Certainly --

Dr. Fauci. If --

Mr. Dingell. So we agree. Doctor, my time is limited, and I am trying to get this through here. So who has the responsibility for defining the level of risk and defining what ought to be done to protect the American public and the world against runaway

infections caused by antibiotics that no longer work on drug-resistant bacteria? Does anybody have this authority or not?

Dr. Frieden. Both the FDA and the USDA.

Mr. Dingell. They do?

Dr. Fauci. Yeah.

Mr. Dingell. The Orphan Drug Act was written in 1983 to encourage pharmaceutical companies to develop drugs for diseases that have a small market. This was done through a series of incentives. FDAAA, the 2007 reauthorization of the FDA user fee programs included provisions intended to strengthen the antibiotic pipeline through the orphan drug program. How effective has the orphan drug program been in your research and development work related to drug-resistant bacteria? And what cooperation has it induced on the part of manufacturers, feed manufacturers, or antibiotic producers or farm organizations?

Dr. Fauci. Certainly, the Orphan Drug Act has incentivized the development of drugs of various types.

Mr. Dingell. Now you have said that this is incentivized. What particular incentive has it produced to do research and development work related to drug-resistant bacteria?

Dr. Fauci. The basic research that we do feeds into a company wanting to develop a drug for a, quote, orphan disease, a disease that is a relatively rare disease.

Mr. Dingell. Do you make it available to them automatically? Is it made available to them by the FDA, or is it available by the

Department of Agriculture or just sort of catch as catch can, and we hope they learn about it in some way so that they can do something about it? And who is in charge of that?

Mr. Pallone. Mr. Chairman, that has to be the last question. He can answer this, and we will move on.

Dr. Fauci. When we provide the assets that we have, we essentially make it available for anyone who needs it or has a reasonable project.

Mr. Dingell. So if they think they need it, they come by and see you.

Dr. Fauci. They do.

Mr. Dingell. If they don't think they need it or there is no incentive for them to come by, they don't come by.

Dr. Fauci. Correct.

Mr. Dingell. Well, Mr. Chairman, this is a very interesting subject. I commend you for the hearing. I think we have to have some more, got to learn a little more.

I don't want our two very fine panel members to think that I have in any way been trying to demean them. I think that we need a great deal more knowledge on this before I am going to feel comfortable on the subject.

Mr. Pallone. Thank you.

Gentleman from Missouri, Mr. Blunt.

Mr. Blunt. Thank you, Mr. Chairman.

I agree with the chairman emeritus; this is a good hearing.

I make take a different tact on this same topic.

Several questions came to mind as Chairman Dingell asked his question, and one would be do, we know that the food chain, the animal food chain, doesn't get less safe if you don't put certain antibiotics in the food, in the system; how do we know that? I mean, there are veterinary guidelines on these antibiotics, so how do we know that it doesn't have the opposite effect?

Dr. Fauci. Mr. Blunt, if you don't mind, I would like to finish the answer to a question that might feed into what you were saying. The issue is, if you give antibiotics to anybody, an animal, a human, or whatever, you will unequivocally ultimately induce the recurrence of a resistant microbe. The real question --

Mr. Blunt. Isn't it true that antibiotics to animals, you don't have much of a chain of lifespan here in animals.

I agree with you, if you and I took a antibiotic for 30 years or 3 years, it might make a difference. But we both know that that is the not the processing system for animal, but let's not go there, that you are going to induce in the individual animal itself an antibiotic reaction because they have had antibiotics for a long time, because the process just doesn't go that long.

Dr. Fauci. With all due respect you, can -- I can have an upper respiratory tract infection, and I can take an antibiotic that is suboptimum or not the right antibiotic, and in 10 days or less, I could have a resistant microbe.

Mr. Blunt. Does that mean you shouldn't take any antibiotics?

Dr. Fauci. No, I am not saying that.

Mr. Blunt. I think you are answering Mr. Dingell's question instead of mine. Aren't there American veterinary guidelines on antibiotics to animals?

Dr. Fauci. That is not my area of expertise of antibiotics to animals.

Mr. Blunt. Then why wouldn't that be something you would like at as you look at this Get Smart, know when antibiotics work on the farm program; why wouldn't you look at the veterinary medical association's guidelines on judicious use of antibiotics if it is not your area of expertise?

Dr. Fauci. No, actually, Mr. Blunt, that is actually more of a CDC issue than -- no, it is. I am not trying to pass it off.

Mr. Blunt. Dr. Frieden may answer the question.

Dr. Frieden. Thank you.

The basic question is, we know that there is no disagreement about certain things, so we should start with those. First, we know that no one disagrees with the need to treat infections in humans and animals that are responsive to those infections. Second, there are evidence-based preventive antibiotics that are sometimes needed in the situation of outbreaks or other similar situations. Third, there is a clear theoretical risk of -- well, there is a known fact that the more antibiotics you give, the more

resistance you will have.

The theoretical risk is whether those resistant organisms that emerge in animals and persistent in animals will cause human disease. And on that, there is some evidence, as I have indicated several times, that it occurred in Europe, and there is less evidence in this country.

Mr. Blunt. But, Doctor, aren't there animal antibiotic guidelines? Am I wrong? Isn't the relative processing life of most food animals pretty short? So the more you give in a short period of time, I would think the veterinary medicine guidelines would have more impact there than the more you would give over a longer period of time. I mean, the processing time or the production time for animal agriculture is relatively short, and there are guidelines for the safety of animals. I guess another question would be, are you sure you don't make the food chain less safe by not giving the proper amounts of additives, including antibiotics, to animal feed prints is the question Mr. Dingell asked appropriately several times.

Dr. Frieden. So two questions, two key points to make, the is that, unfortunately for humans, microbes divide very rapidly. And as Dr. Fauci indicated, even the course of a 10 days antibiotic course, you can have emergence of resistance by a variety of molecular mechanisms. So even relatively short durations of treatment may in fact lead to widespread emergence of drug resistance.

Second, antibiotics are not an essential nutrient. They may increase -- they do increase growth, but they are not an essential nutrient. And there are certainly ways to keep the food supply safe without using antibiotics to promote growth.

Mr. Blunt. I believe Mr. Dingell asked you, does the USDA have the authority to look at animal antibiotics, and I believe you said you didn't know, or what was your answer to that?

Dr. Frieden. Yes.

Dr. Fauci. We said yes, I can't imagine they don't have the authority to do that. There would be no reason why any one would prohibit them from doing that.

Mr. Blunt. Do you have the authority to look at animal antibiotics?

Dr. Fauci. I have the authority but not the mandate; that is not what the mandate of my institute is it to look at animal antibiotics and the agricultural issues.

Mr. Blunt. Not the mandate, but you think you do have the authority, but you don't have the mandate?

Dr. Fauci. Well, it depends on what you mean by the authority. If someone comes in with the grant and wants to do that, it is likely it would get referred to a different agency.

Mr. Blunt. But you believe the USDA does have the authority.

Dr. Fauci. I do believe that, but I don't know for sure.

Mr. Blunt. Thank you, Mr. Chairman.

Mr. Pallone. Dr. Fauci, Mr. Shimkus and I are of the opinion

that you wanted to answer a question that you couldn't, so would you just answer the question?

Mr. Blunt. Is this an extension of my time?

Mr. Pallone. Just answer.

Dr. Fauci. I was almost going to get to the point that, as Dr. Frieden and I had said several times, that there is no doubt that if you give antibiotics to an animal, a cow, bull or whatever, you give them antibiotics in that animal, there is unquestionably going to be the evolution of antimicrobial resistance in that animal.

The critical question that Mr. Shimkus was getting at and that Dr. Frieden answered with regard to a European study is that the question that people are struggling with is that, if you develop the antibiotic-resistant microbe in an animal who is getting antibiotics as part of the feed, is that a danger to the health of humans by transferring of that microbe to the humans? And there is some data that says that that is the case; that is European data. To my knowledge and to Dr. Frieden's knowledge, I don't think any of those studies have been done in the United States. So that is still something that people argue about whether there is any significance to that.

Mr. Pallone. Okay. Thank you.

The Gentlewoman from the Virgin Islands, Ms. Christensen.

Dr. Christensen. Thank you, Mr Chairman.

Dr. Fauci, as you talk about your institute, it supports

basic research, how much of that research is done at universities, and how many of the universities involved in basic research are minority-serving institutions? And do you have any -- well, that question to begin with.

Dr. Fauci. About 90 percent, 89 to 90 percent of all of the research funding that we do goes out to universities on the outside. We fund by grants and contracts virtually all of the primarily minority institutions. Whether or not they have grants in antimicrobial resistance, I would have to get back to you on that, but we readily fund primarily minority institutions in our portfolio.

Dr. Christensen. Another question. Last week at our Spring Health Braintrust with the Minority Health Forum, where you received the award last year, we had a discussion on the lack of adequate minority participation in clinical trials and the need for diversity. In the translational research that is being done in this area, is it diverse enough, because given the different environments, I would assume there are different exposures, maybe different immunities, and maybe possibly even different responses to antibiotics? So do you feel that in the translational research area that we have a good representation of minorities and women?

Dr. Fauci. It really varies. If you look at the clinical trials that we do, for example, with HIV/AIDS, because of the disproportionate disparity of infection among African Americans and, to a lesser extent, Hispanics, we are over-representative

relative to the population, but equitably represented with regard to the burden of disease. That is for a specific disease.

It really varies. There are some clinical trials where, as hard as we try, because of either of location of where the trial takes place or, quite frankly, of some of the mistrust that the minority community has --

Dr. Christensen. We are going to really make an effort through those two organizations and others to work on that.

Dr. Frieden, you mention in your testimony that 10 States make up the network for EIPs, it is a similar question, are these States that have diverse populations, so the information that you get is reflective of the country's demographics?

Dr. Frieden. Yes, it is, they are, and it is. However, this is an area we feel we need to continue to develop to ensure we have adequate representation.

Dr. Christensen. Thank you.

And you talked about helping States respond to outbreaks, and CDC has been very helpful to the Virgin Islands in assisting and investigating some of our outbreaks. As far as the NHSN and the NARMs, are the territories included in that?

Dr. Frieden. I would have to get back to you.

Dr. Christensen. If you find they are not, could you see what you could do to make sure that we are, if it is appropriate?

Dr. Frieden. Absolutely.

Dr. Christensen. Thank you.

Now this question is a little different, because there is a certain concern that I have had, but in the Patient Protection and Affordable Care Act, which you have heard a lot about this afternoon, there are provisions that where hospital-acquired infections occur, the hospitals will not be reimbursed and the providers, I assume, would not be reimbursed for the care that is provided. And there are a lot of antimicrobial products on the market that are used to clean surfaces in the hospitals, and some questions have been raised and brought about whether they are effective.

And I think it is very important if we are going to penalize hospitals and providers to know that these antimicrobials that are being used in the facilities are effective. Do you have any information on whether -- that would suggest that they are not? And do you think that it would be worthwhile for the oversight subcommittee or this subcommittee to take a look at that question, given the importance of it going forward with the new legislation?

Dr. Frieden. This is a complex issue.

Dr. Christensen. I am asking both of you that question.

Dr. Frieden. One of the things that the new legislation does is require reporting of hospital-associated infections, and this we presume will be done through the National Healthcare Safety Network. This is something that we believe is an essential first step in recognizing and addressing infections.

For some infections, like Clostridium difficile, cleaning,

environmental cleaning, may be very important. It may be challenging because it can be hard on the equipment to do it regularly. But this is an area where we work with others, with the hospital systems, to identify effective strategies to prevent the spread of infection or to stop outbreaks once they have occurred.

Dr. Christensen. Dr. Fauci, did you have any?

Thank you, Mr. Chairman.

I yield back the balance of my time.

Mr. Pallone. Thank you, the Gentlewoman from Illinois Ms. Schakowsky.

Ms. Schakowsky. I want to get back to the use of antibiotics in animals.

Both of you in your opening statements talked about and the reason we are here are, public health problems of increasing magnitude; serious public health challenge posed by antimicrobial resistance. Both of you have acknowledged this is a serious problem.

We know that most of the antibiotics that are used in the United States are used for animals, and most of that is used for nontherapeutic use, mainly for growth of animals. You know, we are dancing around this because there is a lot of opposition. This is a highly-charged political issue. And there are many forces who think that, you know, stay out of the farm, leave that alone. And I know that.

But I am trying to understand why we don't have an answer to that question. If all of this use of antibiotics is going on right now in what people are eating and we are facing a serious health threat in this country, explain to me why there has not been any research done in the United States that you can cite, why we don't have an answer to this question, and why, even if we don't have an answer to this question, why nontherapeutic use of antibiotics is so la-de-da if potentially it has this kind of negative effect, dangerous effect?

It feels to me like there is this threat out there; there are so many threats that we can't totally control, but here is one, if we know about it as a potential threat -- I mean, how much money are we spending in the Defense Department and Homeland Security to defend against potential threats? This is a potential threat. At least don't you think we ought to find out if this is a real threat? Will both of you please answer.

Dr. Frieden. I think there is no doubt, as I said before, that there is a potential risk of spread. There is also no doubt that this is not the only way that resistance gets into the community. We see widespread abuse --

Ms. Schakowsky. Why don't we try and find out whether or not this is a source of the problem? And are there any plans to do that? I am a cosponsor of Congresswoman Slaughter's bill. What you are saying is not responsive.

Dr. Frieden. There are several ways to study this, what we

can do is look in more detail what is currently happening, what are the potential additional ways to get more information on it?

Dr. Fauci.

Dr. Fauci. The simplest way to find out, because antibiotics are used in feed for the reasons that you mentioned. We both spoke of the theoretical risk. The real unanswered question, definitively unanswered, is, what is the risk --

Ms. Schakowsky. That is correct. That is what I am asking.

Dr. Fauci. So you are asking a very appropriate question, is that, how do we get the answer to that? It would seem, since there is widespread use of antibiotics in a nontherapeutic, nonprophylactic feed for animal growth, that the only way you can answer the question that you are posing is to stop doing it and see if antimicrobial resistance goes down.

Ms. Schakowsky. Yes, that is right. And are there no farms in which they are not using --

Dr. Fauci. Yeah.

Ms. Schakowsky. So is there not some sort -- are you telling me that science cannot determine whether or not this is a risk to human beings? Is that what you are saying?

Dr. Fauci. No, I am saying you can determine it by stopping the use of it and seeing if the antimicrobial resistance goes down.

Ms. Schakowsky. Is there is no laboratory way? There is no possible way to find out? I mean, I just don't believe that.

Dr. Fauci. No, I understand your question, and I understand your dilemma. If the question is, if an animal is given antibiotic in the feed, will there be resistance? And I could tell you, we could do that study, but I can tell you what the answer is; it is going to be yes.

The question is, does that resistant microbe get out into the community and spread into the community. That is not a very easy thing to get the answer to unless you stop it completely and measure for years what happens.

Ms. Schakowsky. Oh, really?

Dr. Fauci. Yes.

Ms. Schakowsky. No. If we are going to test whether or not the fact of resistant bacteria in an animal then can transfer to a human being --

Dr. Fauci. Right.

Ms. Schakowsky. -- I mean, you can't possibly do it without stopping --

Dr. Frieden. There are at least several ways to do that.

Ms. Schakowsky. Thank you.

Dr. Frieden. One of them is to look for the markers of resistance and see whether the specific way that resistance has emerged among animals is found in people in the community.

I can just give you a little more information. I mentioned several times the European experience with the drug called Avoparcin, which is related to Vancomycin, which is a very

effective drug that has been used to treat severe infections in animals and people. It is the last line of defense for many organisms. So it is very important to preserve Vancomycin for use therapeutically.

It was used for growth promotion in food animals in Europe in the 1970s and was gradually phased out and banned by the European Union in 1997. It was found that community carriage of Vancomycin-resistant strains of one particular microbe, enterococci , which is a highly-resistant organism was quite common before the ban and, after the ban, gradually did decline. That is why we can say there is strong evidence from Europe that suggests that there is spread between feed animals and people in that environment and that restricting the use in that environment for that antibiotic resulted in a reduction in the amount of resistant organisms in the community.

That type of study we would have to look more comprehensively to see what has been done in this country and what could be done by different means.

Ms. Schakowsky. Well, I certainly think that we ought to do that, given the amount of antibiotics that we are feeding to animals and therefore eating ourselves, given that we have this problem. It is shocking to me that this kind of work doesn't seem to even be on the table. Thank you.

Mr. Pallone. Thank you.

The vice chair, the gentlewoman from California, Ms. Capps.

Mrs. Capps. Thank you.

This has been an interesting hearing. Thank you very much.

I have a couple of questions for you, Dr. Fauci, and one, if I have time, for Dr. Frieden.

In today's hearings, we are getting what can be perceived, I believe, by the public as mixed messages. One hand, there is overuse of antibiotics, but on the other hand, we do need greater production of antibiotics as antidotes to antibiotic-resistant strains of bacteria, new antibiotics. And of course, underneath it all, provider and consumer education plays a role in all of this.

How do you reconcile, this is messages for the public, how do you reconcile these messages? And how are CDC and NIH working to devise a comprehensive strategy to combat antibiotic resistance by educating consumers?

Dr. Fauci. It is an excellent question, Mrs. Capps.

There are two fundamental issues. You are asking a question, if we are concerned about antibiotic resistance, why are we trying to make more antibiotics? Well, antibiotics are --

Mrs. Capps. Well, I understand why, but it is a mixed message.

Dr. Fauci. I will try to explain. We can get away from the mixed messages by compartmentalizing it.

You try as best as you can to prevent the emergence of resistance by the public health measures that Dr. Frieden spoke

about.

Unfortunately, we are in a position where there are resistant microbes out there that we are up to the last line of defense with one and at the most two antibiotics that are useful. So there is a clear need to fill, to feed into the pipeline for new antimicrobials.

So I look at it as not a mixed message; we need to do two things simultaneously. We need to put the lid on the evolution and the development of antimicrobial resistance; and then we have got to have a pipeline of drugs to take them. So the message is, we have to get more antibiotics, but we have got to prevent further evolution of resistance.

RPTS JURA

DCMN SECKMAN

[5:32 p.m.]

Mrs. Capps. Do you have a public message that you are putting out for the public on ways to not go and keep asking your doctor for something for a sore throat and so forth, that kind of thing? Is that being done? The PSAs and so forth? I will assume that is happening.

Now from the other side, because I want to get at the concern that has been raised about -- you know, I appreciate the history of the story of the development of penicillin. But pharmacology, pharmaceutical companies are very much working from more of a profit motive today than perhaps they were when some of these initial antibiotics came on to the market, just because they were out of their way to be developed.

Dr. Fauci, can you elaborate on the pathway that you illustrated in your sides from basic research to private development? I would like to know how you are collaborating with private industry in this area, which you noted isn't necessarily the first area that private industry would like to invest in. In other words, you really want some antibiotics to fight these resistant -- to fight the MRSAs and other resistant diseases. How can you, how can we incentivize them to do this?

Dr. Fauci. I can give you actually a concrete, real-time,

real-life example of how we have done that with one particular finding. Since we are involved fundamentally in pursuing and supporting basic research for concept development, we have funded a group of investigators from several of our centers. And they have found a small molecule which has the capability of inhibiting essentially any virus that has a lipid component to its envelope or its outer coating, potentially a really, really important advance. They have no --

Mrs. Capps. Where did you do this, at NIH? You have done this?

Dr. Fauci. We funded them at a university.

Mrs. Capps. Okay. Great.

Dr. Fauci. They made the discovery. So how we are partnering with industry and biotech is that we are providing the resource reagents, the animal models, the capabilities to do a phase one clinical trial for those investigators and hooking them up with biotech companies and then, ultimately, Pharma in order to take what was just a concept into something that might actually be a product. And when, I hope, this comes to fruition of a product, and if and when it does, we are going to provide the clinical trial capabilities to test it in people to see if it works.

So we are really forming a partnership that goes right from the investigator who makes the original observation and develops the concept, up through and including the translation of that through biotech and industry.

Mrs. Capps. And you have a commitment from biotech and industry, because they see the kind of research that you are incentivizing at the university level, if you will, and so they are committed already?

Dr. Fauci. We hope they are committed and stay in the game. If we make -- and that was the point I was making in answer to several questions. If we can facilitate that difficult process from concept to product by any way we can, by making our assets available, other things beyond our control, such as financial incentives, et cetera, it makes that transition from concept to product much easier. We play an important but not an exclusive role in that. There are other components that have to come in to do that.

Mrs. Capps. Thank you very much. That is helpful.

I have a question for you, Dr. Frieden, but I am out of time so we will wait for the next hearing. Thank you very much.

Mr. Pallone. Thank you.

The gentlewoman from Florida, Ms. Castor.

Ms. Castor. Thank you, Mr. Chairman.

I am interested in whether or not you are able to accumulate enough data to track what is obviously a major public health issue, one that has deadly consequences for so many. When I look at the estimates, we have estimates in the number of antibiotic-resistant infections, and then we have estimates in the number of health-care-associated infections.

The CDC's most recent data is that, in the U.S., every year it is about 2 million hospital-related infections, and about 90,000 Americans die from that. And then the other one included in our materials, in America, there are annually about 94,000 cases of MRSA every year with 18,000 deaths from MRSA.

Doctors, do these figures sound about right for you? Is it fair from these figures to conclude that over 100,000 Americans die each year due to antibiotic resistant?

Dr. Frieden. Large numbers. I think the estimate that you gave was 90,000, which is an estimate that has been used before.

As I indicated in my opening statement, there has been progress in MRSA where we have seen a decrease of about 50 percent in serious infections in the hospitals that participate in the National Healthcare Safety Network.

Ms. Castor. So how is the data collected for you to compile these numbers and estimates?

Dr. Frieden. We have two major methods. The one that is more widespread is the National Healthcare Safety Network. This builds on really more than a decade of experience working with hospitals, working with infection-control practitioners, standardizing definitions, encouraging reporting. And now we have 28 States which mandate reporting; 21 of them use the NHSN infrastructure to report. And about half of all hospitals in the United States currently are on board, including many hospitals in States that don't require a reporting publicly yet. And that

reporting we expect to see expand nationally over the next couple of years.

Mrs. Capps. Why would States not mandate that? And why would hospitals not?

Dr. Frieden. It is a recent phenomenon. So 5, 10 years ago, no State mandated it. Again, in a few States, it has been gradually spreading. It is concerning to hospitals. They are worried about reporting from a reputational risk. And the approach has been to make clear that reporting is a good thing, because it helps us to identify problems and then address them.

Ms. Castor. So with the estimates that you have now, knowing that some is not reported and some States don't mandate it, do you extrapolate?

Dr. Frieden. Yes. These are extrapolated from both NHSN and also a network called the ABCs, which allows us to monitor antibiotic resistance to a series of core infections in a representative sample across the country.

Ms. Castor. Should it now become a reportable disease?

Dr. Frieden. Certain strains are mandatorily reportable. There are some that are so common that reporting probably wouldn't be worth the burden, and sampling may be more effective. But for many organisms, reporting -- mandatory reporting is something that is recommended by the Council of State and Territorial Epidemiologists, and is done in most or all States.

Ms. Castor. It sounds like we can do a lot better. What are

you working on or what recommendations do you have to improve reporting so that we are able to track with adequate data?

Dr. Frieden. Thank you. All excellent questions.

One of the things that we have done is to try to use electronic health records to extract information which then is validated a human being but would allow us to ensure that infections are reported reliably or assess the completeness of reporting. One of the things that is essential to make that happen is electronic reporting. So when a laboratory gets a result, it ends up in the medical record. If it is a reportable condition, it ends up with the authorities to which it should be reported.

We also fundamentally need to make better use of the information so that we implement the programs that we know work, and there are some programs that we know can drastically reduce central-line associated infections and other hospital-associated infections; and that we continue to generate knowledge so we can better prevent problems that we don't yet have good tools to prevent, such as community-associated Methicillin-resistant Staph aureus.

Ms. Castor. Doctor, do you want to comment on the data tracking?

Well, I wanted to say, in my district back home, we have a researcher that is working on the antibiotic resistance, and he -- this is Dr. Turos at the University of South Florida. And his

research is MRSA-based, and he is particularly looking at the design and development of nanoparticle-based technology for drug delivery. But in his comments to me in advance of the hearing, he was right on point with what you all are saying of what happens from the basic research level, and then turning that into some kind of new antibiotic. So it is a real issue, along with the lack of funding at NIH, CDC, and DOD in this area. He says it is practically nonexistent, and we simply cannot get the private companies to take any interest.

Thank you very much.

Mr. Pallone. Thank you.

Gentlemen, Mr. Shimkus wanted to ask an additional question. And then if anybody else does, I will allow it, because I don't want to have another round, but I know there is a great deal of interest here.

So I will recognize the gentleman from Illinois.

Mr. Shimkus. Thank you.

And we talked about the CDC, NIH, FDA, USDA. And then, through this hearing, I remembered that the copper industry had been working with the Department of Defense to test copper as an antimicrobial -- however you say it -- killer, antimicrobial killer. And so EPA has just certified -- the Environment Protection Agency approved the registration by the Copper Development Association for copper and copper alloys to make public health claims as being antimicrobial. These claims

acknowledge the fact that copper is inherently capable of killing bacteria.

Have you guys done any look at that? And should you? Is that something that CDC or NIH -- or is this the problem with -- I mean, the Federal Government is huge, and we are doing different things.

Dr. Fauci. Well, let me try to answer it. It may not be the direct answer that you are asking for, but there are a lot of elements that can have antimicrobial activity. The question is to get it into a drug that would not be toxic. That is the issue.

Mr. Shimkus. But this is making a claim that copper being used on surfaces kills microbes. This is what -- and I think we have Federal dollars doing research in DOD through the Department of Defense. All I would say is, you know --

Mr. Pallone. You want to get back to us?

Mr. Shimkus. That is out there. The EPA has said that they can make that claim.

Mr. Pallone. Why don't you get back to us?

Dr. Fauci. We will do.

Mr. Pallone. Mrs. Capps, did you want to ask your additional question?

Mrs. Capps. And I don't want to keep you, because you have already waited most of the afternoon anyway. But my question, and it kind of ties in with before and it can come up in another hearing we might have as well. I was just curious, because,

according to the National Antimicrobial Resistance Monitoring System Data, and that is a mouthful, at least 80 percent of meat and poultry products are tainted with some kind of antibiotic-resistant bacteria. At least that is a study that has been out there. Can I use that as a basis of fact then, that fact?

Dr. Frieden. I am not familiar with that specific statistic.

Mrs. Capps. Okay, well, maybe we will make the assumption, since this is a National Antimicrobial Resistance Monitoring System Data, and they did state that at least 80 percent of meat and poultry products are tainted with antibiotic-resistant bacteria. Tainted. I don't know what level.

My question was that, what bacteria are we testing for in our food? Are we doing any kind of antibiotic-resistant pathogens, like staph or like MRSA, Methicillin-Resistant Staph MRSA? Is it possible to test for any markers or any kind of fact that this might be in food products?

Dr. Frieden. These are all relatively easily tested for in small quantities. If you want to test a large proportion of the food supply, there obviously are logistical and financial implications. This really is the territory of the FDA.

Mrs. Capps. I understand that. But just from the science point of view, and you don't have to agree with the study.

Dr. Frieden. I am not disagreeing. I just don't know.

Mrs. Capps. We can just take that off the table. But

supposing something like that is true, there is the science to be able to pick up the markers or tests within food products? And, again, I am not suggesting that we should, because I understand -- and this belongs to another department. But there is concern about the spread of MRSA and whether or not it is there. And there is a possibility that some research in another department like Food and Drug Administration could do this.

Dr. Frieden. Yes.

Dr. Fauci. It is scientifically possible. It is a logistical issue. It is very difficult at FDA to test broadly, and they only have the capability and the logistical capability of taking a very small fraction.

Mrs. Capps. Exactly. Thank you very much. And that completes.

Mr. Pallone. Thank you.

Dr. Burgess, do I dare ask if you have another question?

Dr. Burgess. Of course, you can.

I just would like to hear from one or both of you, just what are some of the things you see over the horizon, just very quickly, that this committee should be aware of?

Dr. Fauci, you referenced a couple of things with genomics and being able to sequence things very rapidly. We didn't really get into the diagnostics part of this. We only talked about the vaccine part of this. But just very briefly, what is over the horizon that you guys see on a daily basis that we wouldn't be

aware of?

Dr. Frieden. I think, in terms of practice, the first thing is to scale up the proven means of reducing hospital-associated infections and reducing inappropriate antibiotic use. This is something which we have made progress in, but we could make a lot more progress in.

And I have to say, because there has been a lot of discussion of antibiotics in animal feed and use for growth promotion and feed efficiency, that we do not consider use to promote growth an example of judicious use of antibiotics.

I think the directions we are going are, first, to apply the things we know well to reduce infections. And I think we have a lot farther to go there; and second, to continue to generate knowledge on how we can reduce infections through programs, such as hospital-associated programs, electronic health records, reminder systems, control systems that will support doctors in restricting use of antibiotics, and, as Dr. Fauci mentioned, point-of-care diagnostics, which are very important in helping a doctor know right there, if the kid doesn't have strep throat, you don't have to treat them for strep throat.

Mr. Pallone. Okay.

You know, we obviously may ask additional written questions. We will try to get them to you in the next 10 days or so, which is the normal routine.

But members are free to send more written questions or

comments to you. So I just want you to be aware of that.

But I do thank you. I mean, this was a very good hearing. And obviously, members are very concerned about the issue, and the work that you are doing is very crucial.

Thank you very much for your participation. And, without objection, the meeting of the subcommittee is adjourned.

[Whereupon, at 5:50 p.m., the subcommittee was adjourned.]