NATIONAL PRESS CLUB LUNCHEON WITH DR. TOM FRIEDEN

SUBJECT: MERS AND OTHER KEY HEALTH ISSUES TODAY

MODERATOR: MYRON BELKIND, PRESIDENT OF THE NATIONAL PRESS CLUB

LOCATION: NATIONAL PRESS CLUB BALLROOM, WASHINGTON, D.C.

TIME: 1:00 P.M. EDT

DATE: TUESDAY, JULY 22, 2014

MYRON BELKIND: (Sounds gavel.) Good afternoon, and welcome. My name is Myron Belkind. I'm an adjunct professor at the George Washington University School of Media and Public Affairs, former international bureau chief with the Associated Press, and the 107th President of the National Press Club. The National Press Club is the world's leading professional organization for journalists committed to our profession's future through our programming with events such as this while fostering a free press worldwide. For more information about the National Press Club, please visit our website at press.org.

On behalf of our members worldwide, I'd like to welcome our speaker and those of you attending today's event. Our head table includes guests of our speaker as well as working journalists who are Club members. And so if you hear applause in our audience, I'd note that members of the general public are attending, so it's not necessarily evidence of a lack of journalistic objectivity.

I'd also like to welcome our C-SPAN and Public Radio audiences. You can follow the action on Twitter using the hashtag NPClunch. After our guest's speech concludes, we'll have a question and answer period. I will ask as many questions as time permits.

Now it's time to introduce our head table guests. I'd ask each of you to stand briefly as your name is announced. From the audience's right, Charles Sniderman, M.D., Ph.D., Washington bureau chief of *Audio Video News*; Varun Saxena, news editor, Fiercemedicaldevices.com, and Fiercedrugdelivery.com; Jamil Alianak [?], board member, World Prevention Alliance; Ruth Katz, director of the Health, Medicine and Society Program of the Aspen Institute, and a member of the CDC Foundation Board;

Anna Miller, associate editor, Monitor on Psychology Magazine; Christian John Lillis, co founder and executive director of the Peggy Lillis Memorial Foundation, and guest of Dr. Frieden's; Donna Leinwand Leger, reporter for *USA Today*, vice chair of the National Press Club's Speakers Committee, and former president of the National Press Club.

Skipping over our speaker for a moment, Doris Margolis, president of Editorial Associates, and National Press Club Speakers Committee member who organized today's luncheon. Thank you, Doris. Faith Mitchell, president and CEO of Grantmakers in Health and guest of Dr. Frieden's; Susan Heavey, correspondent for Reuters; Carolyn Block, publisher and editor and editor Federal Telemedicine News; Hideomi Kinoshita, Washington bureau chief of *Kyodo News*.

This time last week, Dr. Tom Frieden was busy cramming for his July 16th appearance before the House Committee on Energy and Commerce. The director of the Centers for Disease Control, Dr. Frieden had been summoned to Washington to answer questions about the startling and potentially dangerous lab errors at the CDC. And while that topic is likely to come up again here today, Dr. Frieden joins us to explore a much bigger and broader issue looming worldwide health threats including the pathogens that put modern medicine at risk.

He will discuss what can be done about the Middle East Respiratory Syndrome corona virus, or MERS, a disease that has no known cure and has recently immigrated to our country. MERS haunts the Arabian peninsula and now is showing up in travelers to other destinations far away. The virus's recent arrival in the United States sent hundreds of CDC staff into emergency mode, and some now refer to this illness as public enemy number one.

Other key issues that Dr. Frieden will tackle this afternoon include the dramatic increase in the number of measles cases in America, and the growing threat that dangerous new pathogens pose to world health. These diseases can hitchhike rides and crisscross the globe in a day.

He also will update us about the new program the CDC launched three weeks ago to combat drug resistant pathogens. Some of these killer microbes jump from animals to humans, and a growing number of them are resistant to all currently known drug treatments.

Dr. Frieden has been director of the CDC since June 2009, a physician with training in internal medicine, infectious diseases, public health, and epidemiology, he is especially well known for his expertise in tuberculosis control. From 1990 until 2002, Dr. Frieden worked for the CDC starting as an epidemic intelligence service officer at the New York City Health Department. Fluent in Spanish, he is a graduate of Oberlin College and received both his medical degree, a master's of public health degree, from Columbia University. He completed infectious disease training at Yale University. Dr. Frieden has won many awards and honors, and has published more than 200 scientific articles.

His talk today is titled, “MERS: Public enemy number one?” It’s with a question mark. Dr. Frieden last appeared at our podium last September. Ladies and gentlemen, please join me in welcoming back to the National Press Club Dr. Tom Frieden, director of the Centers for Disease Control and Prevention. (Applause)

DR. FRIEDEN: Thank you very much. It's great to be here and thank you so much to the National Press Club, to President Myron Belkind and Doris Margolis for the invitation and arranging it. And thanks to all of you for your interest in health.

And what I'd like to do is talk to you about some of the biggest threats facing us today. Some of you may have heard about problems at the CDC laboratory. Well, we've had two safety lapses in recent months. These lapses should never have happened. The CDC laboratories are some of the best scientifically in the world, and now we're taking rapid and decisive action to make sure that they're also some of the safest laboratories anywhere in the world.

I'll be happy to talk about that later, but right now I want to talk a little bit more about some of the challenges that we face. Sometimes, at CDC, problems like the one that has come to light recently, occur because people are so used to working with danger. We're currently mounting a substantial response in West Africa where three countries in that region are battling ebola. There have been more than a thousand cases, and more than 600 deaths from ebola virus.

Recently, I walked through our ebola unit to talk with some of the people who are deploying to West Africa, and we shared some common experiences. I had been at a place called Python Cave in Uganda which is, as you might imagine, a cave with a very large python in it, about 15 feet large, and about 10,000 bats and those bats, it turns out, our researchers identified, have about a 5 percent infection rate with the Marburg virus. Marburg is just like ebola except it hasn’t had a movie made after it. But it’s similarly fatal and there were two infections, one fatal, one not, a few years back. And our staff went in there to try to figure out and understand how the bats were moving around the region and what might be able to be done to control Marburg there.

And I asked them, “Weren't you scared to go into this cave that had 10,000 bats, lots of them with Marburg, an often fatal virus and this enormous python?” And they say, “Oh, the python didn’t worry us and the bats didn't worry us because we were wearing those moon suits. And the Marburg didn’t bother us because we have the protective equipment on. The cobras worried us.” And underneath their moon suits, they had to weather leather chaps so that if they had a cobra strike, they wouldn’t be killed by it.

So sometimes that kind of experience does make people too used to risk. And we have to always remember that above all, do no harm, it needs to be more than a motto. It needs to be an organizing principle for all of our work.

Now, like other healthcare workers, I have my personal experiences with risk. Some time back, I was working in rural Latin America on public health programs in communities, and I'm sorry to say this over lunch, but I won't go into details, communities that didn't have great sanitation. And I became extremely ill. It was in the brief period between medical school and starting internship and residency. And I had learned in medical school what a rigor was, but if you've ever had a rigor, you understand that it's not a shaking chill, it's a violent shaking chill, so violent that the bed shakes. That's the definition of a rigor. And it's a reflection of having gram negative bacteria in your blood. And I became quite ill. I returned to the U.S. feeling a little bit better to start my internship and I was testing and found to have an organism called shigella, which is from poor sanitation. It had been in my bloodstream, I was very ill with it. It's highly infectious. In fact, 10 or 20 organisms of shigella can infect another person. And just give you a sense of scale, you can fit about a million organisms on the head of a pin.

So, when I went in for testing, the doctor said, "Well, you've got shigella, they did test for it. And it's resistant to every antibiotic known." I said, "Well, I have to start my internship." (Laughter) and the infectious disease attending said, "You need to go home." But we always want to be part of the solution, and in health that can sometimes be part of the problem.

Now, a little footnote to that story, that episode of illness, shigella is self limiting, so I did eventually get better. Not as quickly as I would have liked, but I did get better and recovered completely. About a year later, ciprofloxacin, the first fluoroquinolone, came into the market and two years later, I wrote an article I published in the *Journal of the American Medical Association*, JAMA, on the widespread inappropriate use of oral ciprofloxacin. It took exactly two years to have a new wonderful medicine that has an important role widely overused.

So, I have a quiz for you. What do these six organisms all have in common besides the fact that they're all infectious diseases? That's too easy. MERS, ebola, measles, multi-drug resistant tuberculosis, c. dif, or clostridium difficile, and CRE, or carbapenem-resistant enterobacteria. Any guesses for what these six diseases all have in common, these six infectious diseases? Yes?

__: First of all, they're preventable.

DR. FRIEDEN: They are preventable, yes. They are all preventable. That's one thing they have in common. How about how they spread? Is there something common? You've got ebola from maybe bats, you've got MERS, maybe camels, you've got--?

__: Airborne?

DR. FRIEDEN: Some are airborne, some are not. Yes?

__: Zoonotic?

DR. FRIEDEN: Zoonotic? Three-quarters of the new infections we face are Zoonotic, so it's a good guess. But not all are Zoonotic, no. Any other guesses? All right, well they're all very importantly spread in hospitals. We can be part of the problem if we're not careful. All of them, and I'll talk a little bit more about that.

Now, when I went to medical school, they taught me to use some really fancy words. I know reporters never use fancy words, but we don't say we gave it to them in the hospital. We say it's nosocomial. That's much more polite, right? And we also don't say the doctor made him sick. We say it's iatrogenic. So this is a nice, fancy 50 cent word that will avoid an uncomfortable truth. And then there's my most favorite of all, we know exactly the cause of his illness. It's idiopathic. Idiopathic means we don't know what causes it. (Laughter) Another definition of idiopathic is the patient is sick and the doctor is an idiot. (Laughter)

Now, MERS is very concerning because like SARS, which occurred a decade ago, it has a high case fatality rate and the case of MERS, it may be as high as 30 percent. MERS also could cause significant, not only illness, but economic dislocation. SARS cost the world more than $30 billion in just three or four months. We're learning more about MERS and that quiz I gave earlier was actually the key lesson we've learned. As we've worked closely with the Saudis and we're now working very closely with them on a variety of investigations and control measures, we've found that the overwhelming majority of MERS cases in recent months, or in the past six to twelve months, have been associated with hospitals. They've been spread in hospitals; patients, staff, visitors, others associated with hospitals.

That's bad news and good news. Bad news because it shouldn't have happened and we should be able to prevent it. But good news because we know how to turn off that tap. We know how to protect healthcare workers and others through infection control measures. And I received an email last week from the Saudi Minister of Health to our staff who reported that in the past ten weeks, they'd not had a single case of MERS in a healthcare worker now that they've implemented stringent infection control measures. When you know how something's spreading, you can stop it.

And there's still more we don't know. We still don't have a prevention, we don't have a cure, we don't have a vaccine. We still don't know how it's jumped from animals to people. It does seem that camels have perhaps been infected by bats and perhaps have something like MERS. Whether it's direct contact with camels or camel products, we don't know, but we're undertaking studies to find that out so we can better prevent it. The more we understand something, the better we can prevent it.

But the next pandemic is not likely to be MERS unless it mutates to develop the capacity to spread easily from person to person. It may or may not be an avian influenza like H7N9 that emerged in China a couple of years ago. And it's a wonderful story of how we have global collaboration. We've already completed clinical trials on a vaccine against this new avian influenza virus.

But maybe the thing that we are most at risk for is not the thing that we don't know, but something that's hiding in plain sight, something that could kill any of us, something that could undermine our ability to practice modern medicine, something that could devastate our economy and something that could sicken or kill millions. Now, someone here in this room, Christian Lillis, knows about this problem. Christian's mother, Peggy Lillis, was a beloved kindergarten teacher. She went in for a routine root canal procedure. Within a week, she had sepsis, that's an infection in the blood stream from c. difficile, an infection that complicates antibiotic treatment. And tragically at the age of 56, she died.

Christian and others have carried the standard to make clear what is the human face behind the tragedies that we read about. Because in public health, we're at our best, as Bill Fage has said, when we see and help others see the faces and the lives behind the numbers. I think of Nile Moss, a 15 year old who loved music, had a congenital abnormality, a malformation, not major, and went in for a routine checkup. Two days later, had a resistant bacterial pneumonia and died Easter weekend.

I think of Josh Naham, a young man from Colorado, 27 years old, loved skydiving. Had an injury from skydiving, got infected, began to recover, then developed a highly resistant organism and also died at the age of 27. Josh's mother, Victoria, as Christian has, has been an activist, an advocate for improving the way we address infections in this country.

Antibiotic resistance could affect any of us. In fact, two million Americans get resistant infections each year; 23,000 Americans die from infections each year, resistant infections, each year. And another 14,000 Americans have deaths like Christian's mother from c. diff. or contributed to by clostridium difficile.

I'm an infectious disease physician. I've treated patients for many infections and I've also treated patients for whom there were no antibiotics left. I felt like a time traveler going back to an era before antibiotics. We talk about the pre-antibiotic era and the antibiotic era. If we're not careful, we will soon be in a post-antibiotic era. And, in fact, for some patients and some pathogens, we're already there.

Antimicrobial resistance is a big problem and it's getting worse. It costs us at least $20 billion a year in healthcare costs alone. And it creates two problems that are worth thinking of a little separately. One of them are the things we usually think of as infections; urinary tract infections, wound infections, pneumonias, things that we think of as the infectious diseases. And we're seeing more and more resistance from those organisms.

But there's a second problem that we may not think of naturally, and that is how important control of infections is to the practice of modern medicine. Six hundred thousand Americans a year get cancer chemotherapy. When we give cancer chemotherapy, we drive down all of the body's defenses so it can wipe out the harmful cancer cells and patients get fevers and serious infections and we're able to keep them in

check until the body's resistance comes back because we have antibiotics that work. So cancer chemotherapy may be at risk.

We have more than 400,000 Americans who are on dialysis. Infections commonly complicate dialysis. If we lose the ability to treat those infections, it will make dialysis much more difficult to do. And modern treatments for everything from arthritis to asthma suppress the immune system because these are partly autoimmune diseases and our ability to give these cutting edge treatments is at risk because of the spread of drug resistance.

Every day we delay means that it will be harder and more expensive to fix this problem tomorrow. Bacteria are evolving very quickly. We need to move quickly to get ahead, to catch up, and to control it. It's possible to keep resistant bacteria from spreading. It's possible for some pathogens to actually reverse the level of drug resistance but only if we act now and act decisively.

What we've seen in some organisms like c. diff. and CRE, that's carbapenem-resistant-enterobacteria, it's a highly resistant organism that can be highly lethal, is that they can be started in a hospital; and in fact, our most resistant organisms start in the hospital. It used to be that almost all of our c. diff. and almost all of our MRSA, another resistant organism, was in hospital. And now we've seen it go out into the community so that now the most common pathogen recovered from patients with cuts and wound infections in the emergency department is a resistant organism, MRSA.

But it's not too late. We know that in CRE, we're still largely dealing with a hospital infection. We can keep it in the hospital and we can shrink the numbers and control it. If we don't, then common infections like urinary tract infections, may be very difficult to treat and we may be, many of us, where I have unfortunately been in that time machine looking at what our world was like before antibiotics.

To stop drug resistance, we need fundamentally to do four things. First, we need better detection. Second, better control. Third, better prevention. And fourth, more innovation. On detection, we need real time systems to find out what's happening around the country. In fact, this week CDC will be launching for the first time a system that will allow any hospital in the country to track electronically, automatically with no extra work after the initial uploading work, all of the antibiotics dispensed in their hospital and all the antibiotic resistance patterns of patients who have infections.

That will allow doctors to be empowered with the right information at the right time to make the right decision so that they can give a patient antibiotics that are needed neither too broad, nor too narrow. So better detection is the first step in controlling drug resistant organisms, to allow us to improve prescribing practices, to identify outbreaks sooner, to figure out if our outbreak control measures are working.

The second key step has to do with control. As with the quiz earlier, much of this is a nosocomial problem, and we have to take seriously above all, do no harm. Too

many infections are being spread in our hospitals. Too many patients are coming in with one condition and leaving with an infection that they didn't come in with. But prevention requires work across many facilities. Even the best of hospitals can't do it alone. They need to intersect with the nursing homes, with the outpatient providers, with other facilities in their communities. And that can best be done with public health departments serving a convening, collaborating and facilitating role. State health departments will be key to reversing drug resistance and will be key to reversing the nosocomial or hospital spread of infections. And many of them are doing it, and they're doing a wonderful job. But we have much more that we need to do.

Third is prevention. The fact is that the quality of treatment for many conditions is nowhere near what we would like it to be. My father was a cardiologist and he used to say that when you see how other doctors practice medicine, you realize how resilient the human body is. (Laughter) Improving prescribing practices in all sectors is crucially important. We recommend at CDC that every single hospital in the country has an antibiotic stewardship program. This means that antibiotics are looked at carefully, that data from their hospital, both resistance patterns and prescribing patterns, is tracked regularly. And if there are aberrations or things that aren't right, they're improved.

We've done a study that suggests that about a third of all antibiotics used in hospitals in this country are either unnecessary or inappropriate. There are enormous differences between one region of the country and another, and those don't reflect under-treatment, believe me, in the areas with lower rates of utilization.

We know that team based care, checklists, reporting feedback, accountability, these are all simple management tools that need to be applied systematically to prevent drug resistance. And we know that many antibiotics that are being used are not necessary. With every medication, whether it's for infectious disease or other, we need to think about the risk/benefit ratio and always think about that ratio. There is no medicine without risks. And we have to balance that risk/benefit ratio. That risk may include drug resistance, it may include c. diff. It may include in the case of antibiotics contributing to the obesity epidemic. That's a current hypothesis for which there is some data; though, frankly, there's some data for lot of hypotheses about what is contributing to the obesity epidemic.

Another area where we've seen a risk/benefit calculation with medications get off kilter is with prescription opiates which turn out to be both extremely addictive and potentially deadly. Take a little bit too much and you stop breathing and can die. So for all of the medicines we use, we have to keep track of that risk/benefit ratio.

Ironically, we under-utilize a lot of medications that have a very favorable risk/ benefit ratio for people at high risk of heart attack, or who've had a heart attack or stroke. Aspirin is only used about half the time. Blood pressure is only controlled about half the time. Even among those at highest risk, statins, which are very effective, are only used about half the time. So we have to get that risk to benefit ratio to make sure that we're above all doing no harm, and on balance doing as much good as possible.

The fourth is innovation. We need to come up with new tools. And while we need new drugs and new antibiotics, they're at least five or ten years away, they may or may not be available. They may or may not work for some of our resistant organisms. And today, we can stop, slow or even reverse much of that drug resistance trend. And there's also innovation needed in tracking resistance, understanding it better, figuring out what works to reverse it.

In the President's budget for 2015, there's an initiative that would be the first of a five year initiative, $30 million a year, that would allow us to build five regional center of excellence all around the country so that we could help doctors understand whether patients have resistance faster, and in real time whether there are outbreaks and how we can stop them. That would help us develop a bank of resistant organisms that pharmaceutical companies and others could use to come up with more rapid diagnostics or better ways to treat them. They would allow us to scale up programs like hospital stewardship programs and improve antibiotic prescribing. And we project that if funded, we would be able to not only save money, but more importantly save lives. We project, based on real data, that with this initiative over five years, we would be able to cut our two deadliest threats in half, both CRE, the nightmare bacteria that's spreading in many of our intensive care units, and c. diff. And we know that because places that have done this right have had that result. We can make this succeed across the country, but only with investment.

In fact, over five years, we project that we could reduce by 600,000 the number of resistant infections by 27,000, the number of deaths from resistant infections, and by $7.7 billion to healthcare costs from it. Public health is a best buy. But we have to act now.

Antimicrobial resistance has the potential to harm or kill anyone in the country, to undermine modern medicine, to devastate our economy and to make our healthcare system less stable. Confronting this has the ability to protect Americans from the moment they're born and throughout their lives. But every day we delay it gets harder and more expensive to reverse it.

It's too late for Peggy, for Nile, for Josh and for 23,000 people who died this year from infections that might have been able to be prevented if we had taken these actions before. And although the problem is big and although it's getting worse, it's not too late to reverse it. By taking decisive action now, we can reverse it and we can protect these antibiotics. The concept of stewardship is an important concept. We're protecting them not only for ourselves, we're protecting them for our families, for our children, and for our children's children. Thank you very much. (Applause)

MR. BELKIND: Thank you, Dr. Frieden. According to a recent report by the FDA, 80 percent of all antibiotics used in the United States are fed to farm animals. This means that only 20 percent of antibiotics, which were originally developed to protect human health, are actually used to treat infections in people. What is being done to address this issue?

DR. FRIEDEN: We want to see rational antibiotic use wherever antibiotics are used. And I think that means, for example, in farm animals or feed animals, that if animals are ill, they should be treated. Using antibiotics that are of importance to humans for growth promotion is clearly something that we, the FDA, the USDA, and the food industry is concerned about. I think that's something that we'll see progress on in the coming months and years. It's more of an FDA, USDA issue than it is a CDC issue. But we do recognize, as CDC, that some of the most resistant organisms we're seeing like CRE, which is a nightmare bacteria. It's resistant to virtually all antibiotics and it covers multiple different organisms that have a fatality rate as high as 50 percent in the hospital, some of our most serious resistant organisms are in the healthcare system, particularly in hospitals. But we want to see rational prescribing everywhere antibiotics are prescribed.

MR. BELKIND: Antibiotic development is not as profitable for drug companies as drugs such as stains and Viagra. How do we encourage pharmaceutical companies to develop new antibiotics to treat these emerging antibiotic-resistant infections?

DR. FRIEDEN: We do really have a problem with the incentives. From a strictly business standpoint, a terrible thing about antibiotics is that they cure people and then you can stop taking them. That's not a model for a highly lucrative pharmaceutical product. You want a product that's going to be taken for a long, long time and that's not what we want with antibiotics. So we have to figure out a way for government and industry to work together so that the incentives for antibiotic production and antibiotic development match the need.

And there have been important steps taken by Congress in the past few years bicameral, bipartisan, new laws in place, that improve those incentives. But it's going to require creativity, it's going to require innovation, it's going to require a dialogue between government and industry thinking about ways to reduce the risk for developers to improve the benefit and to insure that there's a reasonable profit without excessive profit that might result in a backlash. So these are tough issues, but they're important to address.

We do want new antibiotics, they're important. But we also have to recognize that we may or may not succeed. We don't know why the antibiotic pipeline has thinned out in recent years, but it has. Is that because of less investment? Maybe. Is it because the low hanging fruit has all been plucked and it's going to be harder to make antibiotics in the future? Maybe, we don't know.

We can't assume that we're going to develop new drugs to get ourselves out of this mess. We have to assume that we have to make rapid progress with the tools we have and preserve the antibiotics we have while at the same time we promote development of new antibiotics as well.

MR. BELKIND: Is CDC looking into natural cures in addition to prescriptions?

DR. FRIEDEN: There's some really interesting developments in a variety of ways to reduce infection. We know that lots of things will reduce your susceptibility to infection, or improve your susceptibility to infection. If you're healthier, if you're physically fit, if you get enough sleep, this improves your overall immune system. And there's some intriguing new data coming out on the microbiome. We sometimes can think of ourselves as at war with microbes. They're the enemy and we try to keep them out. But actually, we've got trillions of microbes in us and they're important for our health and we're just beginning to understand that.

Some of the new tools, some of which Congress funded CDC to expand the use of, called advanced molecular detection, which allow us to sequence the genomes of microbes in real time, some of these new tools are teaching us new things about the microbes that are helpful as well as harmful. In fact, for c. diff. as an example, there are new treatments that involve providing microbes that fight against c. diff. as a way of battling microbes with microbes.

After all, if you go back to the first drug developed against tuberculosis, streptomycin, Sheldon Waxman and his graduate student, Schatz, figured out that there had to be things in nature that fought tuberculosis. Otherwise, you'd have tuberculosis everywhere. So they went into the soil of Staten Island and they figured out that there were bacteria there that produced chemicals that killed the tuberculosis bacteria. So there are ways that we can use fire to fight fire, if you will.

MR. BELKIND: Can the CDC or the AHS take any regulatory steps to enforce responsible use of antibiotics in hospitals?

DR. FRIEDEN: We have to work in collaboration with the healthcare system. And one of the biggest challenges for public health in the coming years is that integration of public health and clinical medicine. At CDC, we've been delighted to have a very positive, constructive partnership with the Center for Medicare and Medicaid Services. As an example, we for many years have run something called NHSN, the National Healthcare Safety Network. And we had many hospitals involved. And then CMMS said, "Oh, and by the way if you want to get 100 percent of your reimbursement, you must participate in NHSN." And suddenly we have 14,000 facilities participating.

And they benefit from that. They are given information that they can act on to improve their care. Just yesterday, the person who's leading much of our work here met with eight different healthcare systems to figure out how can we sustainably achieve the kind of hospital stewardship programs. So it's not so much a question of mandating and forcing, as figuring out together what's needed and then making sure that we have a level playing field so that that gets done. And tools like the National Healthcare Safety Network provide tools to hospitals to improve the quality of their care.

MR. BELKIND: It's September 2013, CDC put out a report, an antimicrobial resistance in which the agency identified new drug development as a pillar of a strategy to combat AMR. Congress is currently considering legislation to facilitate drug

development by creating a new approval pathway for drugs to treat serious and life threatening infections for which there are few or no treatments. From CDC's perspective, which are the infections for which we most need new drugs?

DR. FRIEDEN: Well, we have one success story. Bedaquiline is a new drug that's useful for multi-drug resistant tuberculosis. And the FDA was able to approve that rapidly. There was some controversy about that, but the data was strong and the CDC recommended it and contraindicated is in support of that decision.

We need to look at the organisms for which we have the greatest risk. That includes the whole spectrum. It includes the gram negative rods, which are deadly, things like e. coli, pseudomonas Klebsiella in our intensive care units. But also the gram positive organisms like staph where we have MRSA. So there are a range of organisms for which we need better treatment. And we also need to understand them better. And the tools that we're now using of advanced detection, are fascinating. We're learning that many of our assumptions were real simplifications. That if you have an infection, it may include not just one organism, but a broad range within that species, what is sometimes called quasi species. And how we're measure that in the laboratory may be different from what's actually happening and causing illness in people.

So there's a lot we need to learn about the patterns of disease, not only within the population, but within individual people so we can innovate and target our innovations most effectively.

MR. BELKIND: Perhaps the battle against microbial resistance to drugs will have to be fourth genetically at the molecular level. Can you address some of the steps in this direction that are being taken at the molecular or nano level?

DR. FRIEDEN: Well, I've mentioned CRE a couple of times. Let me give you a little bit more detail, because I think this really illustrates the answer to this question. CRE is carbapenem resistant enterobacteriaceae. You'll be quizzed on that if you want to have a second cupcake, which I recommend.

But CRE is something that we really have not seen before. It is a jumping gene, a plasmid, a part of the genome, a part of DNA sequence, that can move not only between one organism and another, but between one species and another. And not only can it move between species, but it can encode for resistance to an entire class of antibiotics, all of the penicillin and penicillin-like antibiotics, first generation, second generation, third generation cephalosporins. These are our big guns. This is what we've got to protect people. And this organism can spread its resistance to multiple species and multiple antibiotics.

And we've seen a couple of different ways it can be spread. There's a dominant one in this country and a secondary one in this country. And that's an area where we need to do more research, to understand, all right, if that's what the jumping gene is doing, if that is what's causing-- that's what's driving the resistance to our biggest gun antibiotics,

what can we do to counteract that across multiple species for multiple antibiotics?

MR. BELKIND: Have you seen the latest MERS study saying it may be airborne? And your thoughts, please?

DR. FRIEDEN: We're working very closely with the Saudis and with other countries in the region to better understand and control MERS. We have teams on the ground. We've done studies, we did one in Jordan a couple of years ago that was fascinating. It showed that if there were lapses in infection control you had a lot of spread in the healthcare facility. But if you had good infection control, just standard infection control, even if you had several infectious patients, and lots of exposure, you had essentially no spread as confirmed by checking serology of healthcare workers.

So we're still understanding how MERS spreads, how it jumped the species barrier, how it is continuing to seed cases. But from everything we've seen, it's largely been spread in recent years, in the past two years, in hospital and that's largely controllable by a rigorous infection control. And that's good news. That doesn't mean it won't change in the future, but at least that's where we are now with it.

MR. BELKIND: You've called the bird flu safety breaches the most distressing to you of all the breaches. Why is that breach most troubling to you?

DR. FRIEDEN: We had two laboratory breaches at CDC; one was anthrax, where there was potential, probably not, but potential exposure of workers at CDC to infectious anthrax. What happened, basically, was that a laboratory thought they'd killed the anthrax, but subsequently it was not clear that they had. We've done subsequent studies which suggest that though it's not impossible that some of the anthrax may have exposed other people at CDC, it's extremely unlikely. But still, that was a reflection of a set of policy and procedural lapses that should never have occurred, and we're now taking active measures to make sure that we do everything that we can to make sure that the risk of that is minimized.

The H5N1 situation was rather different. Through a means that we're still not sure of in our laboratory, a non-pathogenic, or non-harmful bird flu was mixed up with a harmful bird flu and then sent to a U.S. Department of Agriculture laboratory. All of this work was done in what's sometimes called BSL3+ or enhanced BSL3 laboratories. Very, very highly contained, people wearing what are called packers, very fancy respirators so they don't get infected, people who shower out when they come out.

So there was no risk at any point of a release of this into the community. But the fact that we were dealing with such a deadly virus that could have big impact on agriculture, and that there was a six week delay between people at CDC being notified about this and it being notified up the chain at CDC made me very concerned that we need to do a better job of encouraging a culture of safety, of encouraging people to report problems or potential problems if they have the slightest concern that there may be a problem.

And whatever the reason, we're still investigating that second incident, whatever the reason, the fact that first off it happened in our flu lab and without exaggerating, I can say that our flu lab is as good as any in the world. It's a phenomenal laboratory. So that made me really stunned that if this could happen at the CDC flu lab, where else could something like this happen?

And second, I was deeply disappointed that it took so long to notify. And we're still understanding the reasons for that. What we've done since then is really take decisive action. We've stopped all shipments of all biological materials from all of our high containment laboratories until I personally review and approve the inactivation procedures laboratory by laboratory. We've appointed a single senior scientist at CDC to review those protocols with the help of a working group, and strengthened them before they come to my review.

We have also ensured that we're going to take a look at every aspect of our safety to improve the culture there and improve it. Again, as I said in the beginning, we have not only some of the scientifically most advanced laboratories in the world, but also some of the safest laboratories in the world.

MR. BELKIND: This touches on your previous comments, but let me ask. In a recent hearing, you told Congress that you recognized the pattern of weaknesses within the culture of safety. How were those weaknesses allowed to develop?

DR. FRIEDEN: When we look back at the last few years, we see that there have been isolated incidents. And I believe in each of those isolated incidents, the staff at CDC and I took responsible behavior to address the concern that was raised. And what I missed, and what I think our staff missed, was that these isolated incidents did reflect a pattern, and it was a pattern of insufficient attention to safety in our laboratories.

And that's what we're addressing now. And I think you can hypothesize about the reason. The story I told at the outset about python cave and ebola is likely to be part of it. If you work with dangerous organisms day after day, month after month, year after year, sometimes there is a tendency to get lax. What we have to insure is that though human error may be inevitable, human harm shouldn't be. We should do everything in our power to insure that we-- and we will do everything in our power-- to insure that there are redundant systems in place so that if there is human error, there will not be human harm.

I think the broader lesson is that it's possible to minimize the risk of many things, but it may be not possible to achieve zero risk. And that has a lot of us thinking hard about what makes sense to do in that risk/benefit ratio. If we're balancing a minimal, but non-zero risk against a potential benefit, we'd better be very sure both, that we make that risk as low as possible, and that we have a reasonable expectation that there will be a benefit.

MR. BELKIND: Can you describe the "sweeping changes" that you have initiated at the CDC? And I realize you touched on some of them. You might want to expand.

DR. FRIEDEN: So, we have done a series of things. I've issued a moratorium on transfer of all biological materials out of high containment laboratories. We've closed the two laboratories where these incidents occurred and we will not reopen them until we're insured that they can open safely. I've appointed a single point of accountability to oversee laboratory safety throughout CDC. And he and his group, Dr. Michael Bell, are reviewing first and foremost those applications to lift the moratorium lab by lab. They will work not just as an individual group, but throughout every part of CDC to promote that culture of safety which has to be every lab worker, every supervisor, every lab branch chief and team lead. We will also take disciplinary action as appropriate.

We have convened, and I've invited an external advisory group of all people who've never worked for CDC before to come in and give us a fresh look. Tell us what we could do different or better to improve safety.

We're investigating the incident with flu, that's not completed yet. And we're looking at our function as a regulatory agency. We have something called the Division of Select Agents and Toxins. We regulate over 300 other entities that work with dangerous organisms. And what are the lessons from our experience to make sure that we do that regulation effectively?

MR. BELKIND: Do I hear that-- are you advocating for harsh punishment against those who breach safety in labs? And what can Congress do to improve lab safety?

DR. FRIEDEN: It's really important to balance two competing visions of how you deal with an incident like this. In one vision, you find the culprits and you punish them. In another vision, you fix the culture and you fix the policies and procedures. I don't think either of those on its own is the right away to move forward. On the one hand, you have to insure that you have policies and procedures and a culture that promotes safety continuously, that recognizes that risks are serious and non-minimal and does everything to analyze what are ways to reduce that risk.

At the same time, you look at individual incidents. And if there is negligence, if there is a failure to report, then you have to take appropriate action. I think those aren't either/or. That's a combined approach.

In terms of congressional action, there are observers who have said perhaps there should be a different entity to look at these dangerous pathogens. And I think that's certainly an idea worth exploring. It's complicated to investigate these laboratories, to inspect them, to insure that they do a good job. We do as good a job as we can on that with the Division of Select Agents and Toxins. But we're going to look at that and see are there ways we can do that better?

Several years ago, because of my concern that it would look like a conflict of interest, I asked the Agriculture Department, which also inspects such laboratories, to inspect CDC's labs so that we wouldn't be one part of CDC inspecting another part of CDC. But we're open to all ideas to how to improve safety in these laboratories. And more broadly, I think we have to look at do we have the right number of laboratories? Do we have the right risk/benefit ratio calculations for some of the research that's going on?

MR. BELKIND: You faced tough questions during last week's House hearing.

DR. FRIEDEN: I noticed. (Laughter)

MR. BELKIND: What was your takeaway from what you heard from the committee members?

DR. FRIEDEN: I think the committee very appropriately had concerns. That if something like this can happen at CDC-- first off, how did it happen? Are you going to fix it, and what's happening elsewhere? So I think the questions were tough but fair. And the approach that I'm taking with my staff, and that I encouraged Congress to take, is very much a trust but verify approach. We're going to do things to improve safety, but don't take us at our word. We will review and share the results of that and insure that what we do, we do transparently, openly, clearly. We also find that it's much better to be clear and open about a problem than otherwise.

And I think we have been about these problems from the moment we learned about them. And that will be our way going forward as well. To say here's what we've done, here's what's achieved and not achieved. I would be disappointed, but not surprised, if we identified other incidents in the past, or other things happen in the future. And that may well be a reflection that we're improving that culture of safety and that willingness to report problems rather than failing to correct what is an important issue to address.

So I think the questions were tough, but fair. And we will continue to provide information because we have such important work to do. This work is not done out of idle curiosity. This work is done because anthrax continues to kill people around the world, because anthrax has been used as a biological weapon, because these select or dangerous agents, organisms, are still both spreading in nature and potentially could be used in a bioterrorist event.

MR. BELKIND: We have some media related questions. What is your reaction to the media coverage of recent incidents involving laboratory safety at CDC?

DR. FRIEDEN: I generally think the media has been responsible in their coverage. I sometimes wish it would be a little different, but I don't think that's something that anyone wouldn't say at some point or another. I think the small pox discovery on the NIH campus somehow has gotten conflated in some of the reports. What happened there was a researcher, probably in 1960s, before there was small pox eradication, put

aside hermetically sealed vials of small pox and other pathogens. It was a different era. It was not done out of malice. And it was kept in a cold room for decades, apparently, undisturbed, untouched. And the moment it was touched, the FDA appropriately informed NIH. They appropriately immediately informed us and we mobilized over the July 4th weekend, actually, to make sure that along with law enforcement we were able to go in safely and securely, secure the materials, make sure they were secured at all times, travel-- transport them securely back to CDC then in a controlled environment in the only laboratory outside-- there are two laboratories in the world that are allowed to have small pox, ours and one in Russia.

In that laboratory with the worker who is the most experienced in the world at working with historical collections of small pox, safely open it, analyze it, test it and determined that, in fact, it was still viable small pox. What we will do with that, as we've said from the very first moment it became apparent, is we will fully analyze the genome, and once that genome is sequenced and analyzed, we will then invite the World Health Organization observers in and we will destroy the strains and all of the biologically viable materials associated with the strains. That's one part of the story that I think sometimes has been confused with the other parts that are going on. It really shows CDC staff working 24/7 to protect people and make sure we can understand and control what turned out to be not a risk, but that required a very active response and got that response.

MR. BELKIND: Media related question on behalf of some journalists, why does CDC now prohibit staff members from speaking to reporters without public affairs office oversight despite the fact that in previous times there were no such restraints?

DR. FRIEDEN: As far as I'm aware, the CDC does not prohibit staff from talking to reporters without media staff present. We do like to have media staff present so we can follow up on any questions and make sure that you're talking to the right people. Sometimes, a reporter might ask a question of one part of CDC that might actually be best answered by another part of CDC. So we try to facilitate that. But we really do like to be quite open and the more information there is out there about what CDC does in this country and around the world 24/7 to protect people from threats, the challenges that we have as well as the programs that we're implementing, the better.

MR. BELKIND: We are almost out of time, but before asking the last question, we have a couple of housekeeping matters to take care of. First of all, I'd like to remind you about our upcoming events and speakers. On August 1st, His Excellency, Denis Sassou Nguesso, President of the Republic of Congo, will discuss peace, security and stability of the central African region and oil investments in his country. And on August 4th, we have just announced that His Excellency Jacob Zuma, President of South Africa, will speak at the National Press Club on the eave of the U.S.-Africa Leaders Summit.

Next, I'd like to present our guest with the traditional National Press Club mug. Y can add this to your collection. And the traditional last question: how does your experience appearing before the National Press Club compare to your experiences last week before Congress? (Laughter)

DR. FRIEDEN: The food was much better here. It's a pleasure to be with you. It's a pleasure to share with you what CDC does because despite the recent incidents, the fact is that CDC has more than 15,000 staff. We work in over 50 countries and every state in the U.S. We provide two-thirds of our resources to state and local entities. And we're there 24/7 to protect people from threats, whether they're infectious disease, environmental threats or chronic diseases, cancer and heart disease, whether they're intentionally created, manmade or naturally occurring, or they're in this country or anywhere in the world. And we do see the press as a vital partner in providing information and shedding light on the important health challenges that we face. So thank you all so much. (Applause)

MR. BELKIND: Thank you all for coming today. I'd also like to thank National Press Club staff including its Journalism Institute, and the Broadcast Center for helping to organize today's event. Finally, here's a reminder that you can find more information about the National Press Club on our website. Also, if you'd like to get a copy of today's program, please check out our website at press.org. Thank you, and we are adjourned. (Sounds gavel.)

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