



CENTER FOR NATIONAL POLICY

**“WMD TERRORISM:
THE BIOLOGICAL THREAT”**

FEATURED SPEAKER:

**DR. MARGARET HAMBURG,
NUCLEAR THREAT INITIATIVE**

**BRIAN FINLAY,
STIMSON CENTER**

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MS. JENNIFER COLLINS-FOLEY: Good afternoon. Welcome to the Center for National Policy. I'm Jennifer Collins-Foley and I'm the executive director here at CNP. And in the current U.S. election environment, we're hearing a lot from the candidates about terrorism and nuclear weapons proliferation and discussions of biological weapons and their potential use by terrorist organizations can get drowned out.

Occasionally, though, innovative ideas emerge through the drumbeat. For example, earlier this month, we learned from the Department of Health and Human Services that government mail carriers might be delivering emergency anthrax – anthrax – emergency supplies of antibiotics to U.S. cities in case of an anthrax attack and it's reassuring that people are thinking creatively and with tenacity about this important topic.

So we're very pleased to have with us today two of the country's top experts on this topic, Dr. Margaret Hamburg and Mr. Brian Finlay. Thank you both so much for taking time to come in and talk with us this afternoon.

Let me just say a few words about the Center for National Policy. We are a bipartisan think-tank focused on promoting dialogue and discussion about the most important national security issues facing our country. Our programming covers several different areas, including Asian security, nuclear security, defense transformation, and homeland security.

And we hope that you will join us in some of the upcoming programs. We have a program on the Beijing-Taipei relationship coming up on October 30th. As part of our presidential series, we'll be having a program the day after the election, called "The Peek behind the Curtain" and we'll be reviewing presidential Election Day the day before. And will also be hosting a program on a resurgent Russia on November 13th. So please keep an eye on our website. We'll be sending you invitations.

We have with us today Dr. Margaret Hamburg, who previously served as the NTI's vice president for the Biological Program and now provides strategic advice and expertise to NTI as a senior scientist. Before coming to NTI, Dr. Hamburg was assistant secretary for planning and evaluation at the U.S. Department of Health and Human Services. She is a physician and expert in public health and bioterrorism, and she served as the commissioner of health for the City of New York and was former assistant director of the Institute of Allergy and Infectious Diseases at the National Institutes of Health.

We also have with us Brian Finlay, who is a senior associate at the Stimson Center's Cooperative Nonproliferation Program, which is a multifaceted program designed to accelerate existing efforts and design innovative new initiatives aimed at

more rapidly and sustainably securing dangerous nuclear and biological weapons, materials, and expertise.

Prior to joining the Stimson Center in January 2005, he served as director of the Threat Reduction Initiative as a senior researcher at the Brookings Institution, and a program officer at the Century Foundation. Before emigrating from Canada, he was a project manager for the Laboratory Center for Disease Control in Ottawa and he holds a Master's from the Norman Patterson School of International Affairs at Carleton University, a graduate diploma from the School of Advanced International Studies at Johns Hopkins, and an Honors Bachelor's from the University of Western Ontario.

So we're going to ask each of our speakers to talk for about 10 to 15 minutes and then we'll open it up for some questions.

We didn't decide who was going to go first. Would you like to go first?

DR. MARGARET HAMBURG: Okay. Well, it's a pleasure to be here. It's my first time here and I see a number of friends and colleagues in the audience, so I apologize for telling you things you already know.

But I thought that perhaps I would start by framing the issue a bit, talk about the nature of the biological threat, quickly outline some of the key elements of a national strategy to address this important concern and some of the key challenges before us. And then Brian was going to sort of target in on some specific aspects of the challenge. I, of course, will be speaking from the perspective of a physician-scientist and a person who spent most of my career working as a public health official, and note that that is a different perspective than many of you in the room that come at this issue from a nonproliferation and arms control perspective.

But I think it's very important that our two areas of expertise and focus come together into an integrated whole, because successful solutions to this problem require both understanding the biological nature of this threat and how it's different and its important security dimensions.

It is now just about seven years since the first deaths in this country from an active biological terrorism, yet in many ways, as was just indicated, we are a little bit complacent still. It's sometimes a bit below the radar screen of policy-makers and the public. I don't think that we still fully appreciate both the immediacy and the potentially strategic significance of biological weapons, and our country is not prepared to cope still with the potential consequences, despite quite significant efforts to improve U.S. biodefense capabilities and extensive new investments.

Clearly, another attack could occur at any time from many potential sources and using many potential biological agents. And clearly, the magnitude of such an attack could be much greater than what we have seen before.

In the near term, it's my personal opinion that conventional attacks, using bombs or some kind of explosives, is probably the most likely mode of terrorism, but there are many reasons to believe that biological agents may be an increasingly attractive approach. Certainly, they can produce large numbers of casualties, potentially on a scale to devastate whole cities, regions, and possibly the entire nation and beyond.

And even without large numbers, attacks with biological agents, especially covert ones, can produce terror and panic in ways that are enormously disruptive and costly. And we certainly saw that with the anthrax letters, where the consequences extended far beyond the paths of those anthrax-containing letters. And I think we all can recognize that attacks using communicable diseases, diseases that can spread person to person, would be even more terrifying.

The truth is that there's probably no single type of terrorist attack, no matter how horrifying and catastrophic, that could threaten the very stability of our society and its institutions in the way that biological weapons could, except, I think, for nuclear weapons.

But unlike nuclear weapons, biological weapons are relatively inexpensive, easy to produce, and significant damage can be done even in the absence of large quantities of material or an elaborate delivery mechanism. And pathogens suitable for biological weapons can be concealed and transported with little difficulty and bioweapons facilities can be hidden within routine research laboratories, pharmaceutical manufacturing sites or even breweries.

Certainly, the organisms of concern are commonly found in nature, as well as legitimately studied in government, academic and industry labs. And for some potential terrorists, biological agents may have special appeal because the delayed onset of effect can make it easier to escape detection.

Adding to the challenge is the fact that while extraordinary advances in modern biology and life sciences research offer great hope to improve health and prevent disease, they also offer the tools to malevolence, misapplication, or sheer inadvertence to create new and more dangerous organisms, as well as improve mechanisms for delivery.

Overall, the reality is that access to materials and the know-how to produce potentially very serious biological threats becomes easier and more sophisticated every day. And this has profound implications for both science and security.

We know that al Qaeda is working to get these weapons. In fact, Osama bin Laden is reported to have said that it's a religious duty, not just biological weapons, but weapons of mass destruction more inclusively, but still – and we know that a rudimentary anthrax facility was found by U.S. forces in Kandahar, Afghanistan, and while that particular facility has been disrupted, the desire to pursue bioweapons is certainly still intact.

In 2003, al Qaeda issued a fatwa, authorizing the use of biological, chemical, and nuclear weapons against non-Muslims and in 2006, al Qaeda represented its call for scientists to join the jihad to help produce WMD.

So what kinds of things are we most worried about? In theory, a wide range of biological agents could be intentionally used to create harm. Most of the focus in planning to date has been on those subsets of organisms felt to pose the greatest threat to civilian populations: anthrax, smallpox, plague, tularemia, viral hemorrhagic fevers, and botulism.

And while we largely think about bioterrorism as an infectious disease-related threat, the future of bioweapons does not have to be so. And it's important to recognize that expanding insights into various regulatory and other systems of the body offer new opportunities to develop tools that will disrupt critical functions for life or behavior. And actually, we know that in the bioweapons program of the former Soviet Union, they were actually working on neuromodulators and endocrine disruptors as a potential strategy.

And, as I mentioned briefly already, with advances in biomedical science, including synthetic biology, recombinant DNA techniques, genomics, and the like, the possibilities get much greater. The explosion of knowledge about the fundamental building blocks of life and how to manipulate them give new understandings of really staggering and unpredictable power. And along with this, comes this spread of expertise and equipment to support biotechnology and biological manufacturing processes.

So it is a rapidly evolving set of concerns that very closely link advances in science with a changing threat environment.

I won't go into all the different possibilities that one can conjure, but it is a frightening set of scenarios when you sit down and look at the scientific literature and think about how some of those important advances, in many instances, advances that are critical to developing new drugs, vaccines, and diagnostics to, in fact, prevent and control disease, could be misapplied if your intention was to do harm. And I think one interesting thing for us to potentially talk about this afternoon is how do we, as a society and as a global community, deal with this important set of threats?

From a security perspective, it's very tempting to try to figure out how to limit the kinds of research that could be misused or distorted in damaging ways, but it's quickly apparent that while the potential for misapplication is real and present, that the potential for good is far more significant and needs to be supported. So we really cannot define dangerous science and forbid it. We really cannot take microorganisms used in some of this research and put padlocks around the Petri dishes or even around the laboratory walls.

So we really need to think about ways to create a new ethos among scientists, so that they understand the implications of their work and provide a set of mechanisms for self-governance. We also have to bring the scientific community into discussions with

policy-makers, so that we can develop appropriate rules and regulations that can hopefully limit access to dangerous pathogens and develop standards and guidelines for oversight of research, but without trying to apply a guns-and-guards kind of model, which is often attempted in this context because it's so familiar to the arms control community in the context of nuclear threats.

Let me just quickly bullet a couple of critical elements when we step back and think about a national strategy for addressing the bioterrorism threat. Clearly, prevention is key. Some of the kinds of things I was just talking about represent important elements of prevention in the biological context, in terms of reducing access to dangerous pathogens and responsible stewardship of science.

It also means greatly enhancing our intelligence about the threat. If we could find better human sources – we're not going to be able to look from a satellite and see movements of pathogens to give us clues about what's going on. So it has to be on the ground and it has to, again, integrate scientific understanding and a medical public health context with an understanding of intelligence concerns.

Prevention is key and more than anything, we hope to be able to prevent an event from occurring in the first place, but it's a daunting challenge, and so we also need to always prepare. Preparation, in this case, means strengthening the public health infrastructure for disease surveillance, so that we can have rapid detection and response to an emerging threat.

Whether it's naturally occurring or intentionally caused, this is critical to health security. And with a biological attack, we may not know ever, or for a very long time, whether an outbreak is an intentional, deliberate event or a natural event. So we have to think locally, regionally, nationally, and internationally about strengthening our capacity for early recognition and response. With that must come the capacity for care. It was just mentioned about using postmen to deliver critical drugs or vaccines.

We have to think out of the box. We have to recognize that existing health care facilities in this country and around the world are inadequate to surge for mass casualty events of the type that we may see. We have to think about ancillary sites of care, non-traditional providers, innovative strategies to get medicine to places where it might be needed. And we have to have an educated public because the public is such a critical and essential partner in actually implementing the response to any event.

And we have to invest in research. I already mentioned the importance of research, but it is really the foundation of all of our future preparedness and strategies for effective prevention. And while there have been many important activities underway, beginning pre-9/11 and the anthrax letters, but post-9/11 and the anthrax letters, efforts have since been greatly enhanced. Many good programs in these different areas that I've mentioned are underway, but there still is much more to be done and also in a constricting economic environment.

This is really a time when we have to examine the programs and policies that are in place and assess which ones are working and which ones aren't, and have the courage to step away from some that are proving less valuable and really invest and extend those that are making a difference.

Let me just conclude by saying that most of my comments have focused on the importance of preparing and preventing a biological attack, but as we move forward, we should recognize that Mother Nature is a very effective terrorist. And if we look at the three most deadly events in history, they've all involved infectious disease.

Black Death took about 25 million. The outbreak of flu in 1918-1919, the so-called Spanish Flu, took between 50 and 100 million worldwide. And we are currently living out the AIDS epidemic, which has already taken 25 million lives and it's on a course to have a much higher toll.

So I think that it is important to have a very deep respect for mother nature, to recognize that while we prepare for a bioterrorist attack, while we think about the proliferation of biological weapons, we do so in a context of the existing and anticipated burden of naturally occurring disease, and that we use our dollars wisely to put in place the kinds of programs and policies that will support efforts to manage those kinds of naturally occurring events, as well as those intentionally caused.

And I think that if we do so, we can also do some amazing things for the globe in terms of improving health conditions around the world and reducing the kinds of conditions that, in fact, foster, aid, and abet the development and promotion of terrorism, hostility, and deadly violence. Thank you.

MS. COLLINS-FOLEY: Thank you. It was kind of an optimistic end to a very – (laughter) – thought-provoking beginning. Brian?

MR. BRIAN FINLAY: Thanks. Well, I'm very grateful to you for the opportunity to share the stage today and I'm particularly happy to share the stage with Dr. Hamburg. We're very lucky to have her here. For those of you who – and probably everyone in the room is aware of Dr. Hamburg's long history on this. She really is one of the, I think, wise women in this country and around the world on these issues. So it's a great privilege for me to share the stage with you, Peggy.

DR. HAMBURG: Thank you.

MR. FINLAY: To Peggy's initial point, I am actually one of those knuckle-dragging arms control types, so I should caveat all of this by saying I have zero experience in public health. And so I do really come at this from – aside from maybe – (inaudible) – so I do really come at this from a very different perspective, but one that I think really complements some of the things that Peggy, you talked about.

With your permission, Jennifer, I'd like to kind of discard the usual talking points on bioterrorism. I think Peggy really covered very well the government responses to this. And so I'd like to look maybe at a different constituency and one that I think is an oft times forgotten constituency in this broader debate on bio-proliferation and bioterrorism, and that is simply industry. And I'd like to do so by telling you a little bit about Botox.

Now, I don't look at you for any particular reason, when I say this. (Laughter.) But once you, I think, get to look at this particular product and kind of get past the giggle factor surrounding Botox and past the debates as to whether Katie Couric and Simon Cowell are users or not, I think that this product, and increasingly, a growing number of competitor products to Botox, represent or are indicative of a rapidly shifting environment that Peggy alluded to in her remarks, surrounding this whole area of proliferation and bioterrorism.

These products, I think, illustrate three things, at least to me. One, they represent the complex challenges that we face in trying to ameliorate the threat of bioterrorism and I say ameliorate very pointedly, not to prevent. I think that's going too far, as again, as Dr. Hamburg, I think, pointed out very, very well.

Secondly, I think that these products illustrate the increasingly anachronistic approach that our government brings to addressing the threat of bio-proliferation. And that is aided, frankly, by both a lack of innovation and ingenuity within government, within government policy-makers in the national security world, as well as in the public health world. But to be fair, there is an equal, I think, lack of innovation in the NGO community, in the think-tank community, in academia and elsewhere, when you look at how we might address these threats in a more holistic way.

So let me tell you a little bit about Botox. As you – I think probably everyone in the room is familiar with the Hollywood application of this product. It's the anti-wrinkle treatment. But what some may not be aware of it is that the active ingredient in Botox is botulinum toxin type A. It's the most deadly substance known to man supposedly.

So a few words about botulinum toxin. Ever since *Clostridium botulinum* was discovered by scientists in the very late 1800s, research and development surrounding this toxin has really followed one of three paths. First – perhaps most popularly – governments have used botulinum toxin, weaponizing it into biological weapons. The Germans did it; the Japanese did it; the Americans did it; the Soviets did it, and so on – others as well.

So they weaponized it into biological weapons, and similarly, they conducted research to develop countermeasures to those biological weapons in the event that they were used against them. It was this, I think, that prompted the CDC to put botulinum toxin on the Select Agent list back in the 1990s.

Secondly, we know that terrorists have experimented with and, in fact, used botulinum toxin as an attempted biological weapon. Fortunately, to our knowledge, –

(unintelligible) – the Japanese – (inaudible) – was not successful in successfully weaponizing the toxin, but in fact, we know that in three separate occasions in the early 1990s, they actually tried to use to this thing. They mounted it on the back of a pickup truck with big fans and drove it around the Imperial Palace. They used it outside of a U.S. military base in Japan.

But third – and this is what I think is perhaps most interesting – most recently, the pharmaceutical industry has discovered botulinum toxin. Now, Botox is certainly the most famous of the products to emerge from this realization, but it's not the only one to emerge from it. The Germans have a product similar to Botox; the Brits have a product similar; the Chinese have multiple products similar to Botox, many of them counterfeit products that they actually try to market under the names of the British company and the German company, as well as the American company.

And what I think probably most people in this room are not aware of, when it comes to Botox and these competitive products, is in fact, the lion's share of the markets for these products is not cosmetic. It's actually a therapeutic product. That's what it was initially developed for and that's what the lion's share of the market still today represents, both in this country and around the world – muscle spasm, strabismus. It treats cerebral palsy, the effects of cerebral palsy, headaches and migraines. You've got carpal tunnel syndrome, Botox may be able to help you. Diane Rehm found her voice, in part through the use of Botox.

So it is – as I say, it is a therapeutic drug and it has legitimate therapeutic applications.

Furthermore, botulinum toxin is actually not the only toxin, not the only Select Agent even, that is being used and experimented with and has entered the drug R&D pipeline and indeed, entered the global therapeutic market. Ricin, abrin, conotoxins, tetrodotoxins, the Japanese puffer-fish toxin, all of these are basically in the drug pipeline now, or have found their way into marketed products, not in this country yet, but in other countries around the world. And we anticipate that that is going to change and these products are actually going to enter the U.S. market in the not too distant future.

The important takeaway, I think, is that this product, Botox and competitor products containing botulinum toxin, or other toxins, represent a today multi billion-dollar industry around the world – a multi billion-dollar industry – in virtually every country around the planet.

Now, where you have billions of dollars floating around, you've got a whole lot of interest. And so therefore, we have seen, I think, a proliferation of companies in this country again, as well as in various countries around the world, that are looking at the application of these dangerous agents for legitimate pharmaceutical products.

So who cares? What does this have to do with bioterrorism?

Well, to answer that, let me take a step back and look at the state of biosciences in the world. And Dr. Hamburg, I think you did an excellent job, far better than I can, in describing what that world looks like.

But it's clear that the biotech revolution that we are living in today and that Dr. Hamburg, again, described, has made the world a better place to live perhaps than ever before. Life expectancy over the past 100 years has doubled in large measure because of advances in biotechnology. We have new capabilities to detect and treat illnesses that we thought previously were unbeatable. We have new technology for food production, which is changing the world in many ways.

This revolution, however, is being driven by not the government sector, but by the civilian sector today. And it's largely – the civilian commercial sector is composed of small and medium-sized companies in this country, and again, around the world and these companies, and the number of them, are growing at an unprecedented – an unprecedented – pace.

This means ultimately, that there's a declining share of the technology in the biosciences that is in direct government control. And furthermore, there are practical challenges, I think, to actually getting our arms around. Getting or using this guards, guns, and gates approach is increasingly impossible because we don't know, in many cases, who these companies are. What are they working on? Where are their scientists going? Where are their products going? Where are their technologies flowing to and who around the world is receiving it?

The point is that these dual-use technologies, like the recipe for Botox, are being pushed into more and more hands around the country, which means to me that the simple law of averages would suggest that eventually, something bad is going to happen because more and more people have access to make bad things happen.

So for instance, in 2005, a company called Maine Biological Labs was fined half a million dollars by the U.S. government, given five years probation, for the marketing of unlicensed exports, including viruses and toxins, to Syria.

Three years ago, a New Jersey company called Becton Dickinson was fined for 36 violations of the Export Administration Act for exporting similar products to India.

A Texas company was recently fined – BJ Services was fined for exports of dual-use biological items.

A San Diego company was more recently – EMD Biosciences – fined \$1 million for exporting toxins to Canada of all places.

And in 2004, a company called List Biological out on the West Coast received a mail order request from a physician for raw botulinum toxin. Now that raw toxin was marked for animal use only, but this physician, who as it turns out, had lost his medical

license, decided to use that toxin to mix up his own bathtub variety of Botox, and essentially hop-scotching the purchase of the product, make his own, and injected it into himself for cosmetic reasons, his presumably now ex-girlfriend, as well as his two next-door neighbors. Now, miraculously these four individuals did not die, though court records suggest that they received about 10,000 times the regular dose of a Botox injection.

Now, the motivation for this particular case – and presumably for the cases that I mentioned earlier, the various companies – was greed fed by stupidity, but it indicates, I think, the growing challenges that an individual that has a nefarious intent could actually gain access to these things with relative ease. And that's just within our borders. Globalization, privatization, economic development, rapid transportation, the IT revolution, rapid communications have extended these challenges, as Peggy mentioned, well beyond our borders today.

The number of biotech companies in Europe doubled in just four years. In Brazil in 1993, there were 76 licensed biotech companies. In 2001, there were 354 companies working in the biosciences. We see similar trends in India, in Malaysia, in South Africa, in South Korea, and elsewhere.

Here's the catch. This is not a bad thing. It means that innovation can occur today anywhere in the world. Cuba was the first country to develop a vaccine against meningitis B – Cuba. South Africa was the first to engage in HIV C strain preventative treatments. India is today the largest producer of the Hep B vaccine. And China licensed the first gene therapy.

These are all positive trends, but again, to Peggy's point, the law of averages suggests that eventually, we're going to jump the rails and someone is going to get their hands on a dual-use item that is not going to be good and that can be used ultimately for bio-proliferation and ultimately, bioterrorism.

The difference, of course, is nefarious intent or is it going to be simply a lack of appreciation by one of these peace-loving countries and a company that is intending to do good, but in fact, doesn't fully understand the threats associated with their engagement or ultimately, the product that they are distributing?

Let me go back to, and give you a global example – back to the Botox example. There's a company, a European company, that has made the strategic decision several years ago to begin marketing their Botox-like product, a product containing botulinum toxin, to the Islamic Republic of Iran. Now, this is a country that has been deemed by the United States as a state sponsoring terrorism. There have been accusations in the past that they have intent, if not an active program, to build biological weapons. Now, sharing the product is one thing, but they have gone a step further and are actually now engaging in clinical trials of their product in Iran.

Now, if you talk to FDA and ask them what sort of information is required by a foreign company to actually conduct clinical trials, it's clear that the sharing of information of that European company to the government of Iran may very well have crossed the threshold. How do we stabilize the toxin? How do we use the toxin? That could be used for legitimate pharmaceutical purposes, as the company is intending. This is not a nefarious company. It's a respectable company, but in fact, that information could also be used to promote an offensive biological weapons program.

The bottom line is that this is a global regulatory nightmare. It's not just restricted to the United States. And again, the point is that the threat is changing and we, I think, here in the United States, and countries around the globe, are failing to keep pace with those changes.

A recent Stimson study – and I'm almost finished, Jennifer. A recent Stimson study that we conducted that looked at industry, and this subset of industry and the number of companies that are actually out there working on products like this, showed that the national security agencies, which are being driven by a national security mission, and the public health agencies in this country, whose primary focus is, of course, public health, are operating in deep stovepipes at the very time that they should be collaborating closer.

So let me give you an example of this. This recent Congress has been wrestling very much over the issue of drug reimportation. We reimport drugs from Canada to get cheaper drugs for the people in the United States. It's a great idea in my view, but when we think about this a little bit more through the lens of national security, what are the drugs that we are encouraging to come into this country? Where have they been? We're stretching the supply chain out with drugs that may contain Select Agents that we are giving an expedited pathway into this country.

Another issue that this Congress followed was follow-on biologics. Let's encourage more generic companies to get involved in this research and across the pharmaceutical and biotech spectrum. Again, there is a subset of products out there that we want to know more about these companies that are experimenting with and working on these products, both in this country and around the world, before we give an expedited pathway to anyone.

Expedited pathways are a great idea because it's going to bring cost down, but at the end of the day, we need to be certain who these companies are and whether or not they are working to prevent the illicit transfer of sensitive information or pathogens.

Let me try to end on a positive note as well, if I may. Look, I think at the end of the day, we need to – the U.S. government needs to recognize that the guards, guns, and gates approach is – and I agree completely with Peggy – is increasingly anachronistic. It may have a role on the nuclear side. It may have even a limited role on the biological side, but by and large, we've got to be more innovative on how we approach these threats. That's number one.

Two, I think that the critical – given my previous comments – the critical driver in all of this is private industry. Private industry does not act, by and large, even in this country – look, they’re all good Americans, I’m sure. They all want to do the right thing, but at the end of the day, they are motivated by profit. And we have to figure out how we can tap into that motivation to make them see that they need to take a greater role and responsibility in addressing the national security concerns that are arising from the biosciences.

I have a bunch of ideas, but I’m going to just stop right there.

(END)