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Before the

Subcommittee on Emerging Threats and Capabilities

COMMITTEE ON
ARMED SERVICES

UNITED STATES SENATE

HEARING TO RECEIVE TESTIMONY ON
BIOLOGICAL THREATS TO U.S. NATIONAL SECURITY

Wednesday, November 20, 2019

Washington, D.C.

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5
6 U.S. Senate
7 Subcommittee on Emerging
8 Threats and Capabilities
9 Committee on Armed Services
10 Washington, D.C.

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12 The subcommittee met, pursuant to notice, at 3:04 p.m.
13 in Room SR-222, Russell Senate Office Building, Hon. Joni
14 Ernst, chairman of the subcommittee, presiding.

15 Subcommittee Members Present: Senators Ernst
16 [presiding], Fischer, Cramer, Blackburn, Hawley, Peters,
17 Shaheen, Hirono, and Heinrich.

1 OPENING STATEMENT OF HON. JONI ERNST, U.S. SENATOR
2 FROM IOWA

3 Senator Ernst: Good afternoon, everyone. I want to
4 thank you all for joining us today.

5 The Emerging Threats and Capabilities Subcommittee
6 meets today to receive testimony from Dr. Julie Gerberding,
7 Co-Chair of the Center for Strategic and International
8 Studies' Commission on Strengthening America's Health
9 Security; Dr. Thomas V. Inglesby, Director at the Center for
10 Health Security at Johns Hopkins Bloomberg School of Public
11 Health; and Dr. Tara J. O'Toole, Senior Fellow and Executive
12 Vice President at In-Q-Tel.

13 Our focus today will be to gain a deeper understand of
14 the nature and severity of biological threats to our
15 national security, as well as the preparedness of the U.S.
16 to defend against and respond to these threats.

17 I thank our witnesses for being with us today.

18 The 2018 National Biodefense Strategy identified
19 biological threats, whether naturally occurring, accidental,
20 or deliberate in origin, as among the most serious threats
21 facing the United States and the international community and
22 capable of causing catastrophic harm to the United States.

23 Despite the severity of this threat, I note that a
24 recent report by the Center for Strategic and International
25 Studies' Commission on Strengthening America's Health

1 Security states that the United States remains woefully ill-
2 prepared to respond to global health security threats. I
3 find this deeply concerning, given the potential devastation
4 of a biological event, and look to our witnesses to provide
5 their candid assessment of the U.S. posture and programs
6 focused on dealing with this challenge.

7 Of particular interest is the role of the Department of
8 Defense in providing sufficient biodefense both abroad and
9 at home. DOD has had many biosecurity successes such as
10 securing laboratories in allied countries, providing
11 surveillance of especially dangerous pathogens, and
12 developing lifesaving vaccines for our warfighters. And
13 while this subcommittee is principally focused on the
14 Department of Defense's role in countering the threat, this
15 does not stop at a vaccine. It requires constant research,
16 investment, and planning across federal, State, and local
17 governments.

18 While advancements in biotech research and development
19 have provided innovative solutions for treating disease,
20 developing alternative fuels, and promoting food security,
21 they have also generated new security risks. For example,
22 gene editing technology, new targeting methods, and vaccine-
23 resistant disease could all be used for nefarious purposes
24 by state and non-state actors alike.

25 Another particular area of concern for me in my home

1 State of Iowa is the potential impact of a biological
2 incident in the agricultural sector. A biological attack
3 targeting specific types of crops or livestock could be
4 devastating to Iowa farmers and have a severely negative
5 impact on the Iowa economy. Such an event would not only
6 impact Iowans. Indeed, folks across the country would
7 potentially feel the effects of food shortages, and the
8 American economy as a whole would suffer if our agricultural
9 industry was to be the target of such an attack.

10 Again, I thank our distinguished witnesses for being
11 with us, and I look forward to their testimony.

12 And I will now turn it over to our ranking member,
13 Senator Peters, for his opening statement.

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1 STATEMENT OF HON. GARY PETERS, U.S. SENATOR FROM
2 MICHIGAN

3 Senator Peters: Well, thank you, Chairman Ernst for
4 holding this very important hearing here today.

5 And I want to thank each of our witnesses for taking
6 time to come before us and present your thoughts, as well as
7 answer our questions.

8 There is no question that the threats that we face in
9 the area of biosecurity are vast, they are complex and
10 evolving. Adversarial nation states still retain the
11 capability to produce biological weapons in spite of the
12 Biological Weapons Convention. And now even non-state
13 terrorist groups like ISIS can recruit technically trained
14 scientists to weaponize pathogens as instruments of terror.

15 We are in the midst of a technological revolution in
16 gene editing with CRISPR, which will give scientists an
17 unprecedented ability to modify the genetic code.

18 Finally, we must safeguard against threats to our
19 agriculture and food supply, such as the African swine fever
20 that is spreading at a very rapid pace through Asia and
21 Europe.

22 In recent years, Congress has worked to address these
23 serious threats. The 2017 National Defense Authorization
24 Act required the President to develop a comprehensive
25 biosecurity to recognize the spectrum of threats that we

1 face from natural occurring outbreak of Ebola to its use by
2 ISIS.

3 Published in October of 2018, the strategy is the first
4 acknowledgement of the continuum of threats that we now
5 face. Dangerous pathogens know no international borders,
6 and a public health biosecurity incident is just as
7 dangerous as an attack by a bioweapon.

8 More importantly, the strategy coordinates efforts
9 across the Federal Government to better detect and prevent
10 and, if necessary, respond to a biothreat.

11 While we have made significant progress in the area, we
12 still face a number of gaps in our country's biological
13 defenses. The bipartisan Commission on Biodefense
14 identified numerous recommendations to strengthen those
15 defenses and protect our country from the vast array of
16 biological threats.

17 The Department of Defense plays a key role in
18 supporting the biosecurity strategy, and I look forward to
19 exploring the Department's contribution and hearing today
20 about how we can improve those efforts.

21 So once again, thank you for your testimony here today.
22 I look forward to it a great deal.

23 Senator Ernst: And now we will go ahead, and we will
24 do our witness testimony. Dr. Inglesby, if you would go
25 ahead and start. We will have about 5 minutes for your

1 statement. Thank you.

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1 STATEMENT OF DR. THOMAS V. INGLESBY, DIRECTOR, CENTER
2 FOR HEALTH SECURITY, JOHNS HOPKINS BLOOMBERG SCHOOL OF
3 PUBLIC HEALTH

4 Dr. Inglesby: Thank you. chairman Ernst, Ranking
5 Member Peters, and members of the committee, thank you for
6 the chance to speak with you today.

7 My name is Tom Inglesby. I am the Director of the
8 Center for Health Security at Johns Hopkins and a professor
9 of public health and medicine at Johns Hopkins University.

10 The country faces a range of biological threats that
11 could emerge without warning, whether from nature,
12 deliberate attack, or accident. These threats could include
13 a global pandemic of avian influenza, lethal emerging
14 infectious diseases spreading from person to person,
15 bioweapons threats like smallpox or anthrax, or newly
16 engineered biological threats. Epidemics could be caused by
17 accidents from labs working with viruses like smallpox or
18 SARS or MERS, which are no longer circulating in the world,
19 or from research aimed at creating novel potential pandemic
20 strains of pathogens. The country also faces the potential
21 for deadly large-scale animal outbreaks or plant epidemics
22 that kill important crops.

23 In major human epidemics, there would likely be an
24 urgent need for medicines and vaccines and ventilators,
25 possible pressure to close borders, and the potential for

1 hospitals to collapse under pressure. There could be
2 serious impact on national security and to the Department of
3 Defense with risks to health and life in the force and their
4 families, a surge in need for medical supplies, big
5 challenges to deployments, interruptions to logistics lines,
6 and economic shocks, and other disruptions to the country.

7 The 2018 National Biodefense Strategy sets national
8 priorities for addressing this range of biological threats,
9 and this is forward progress. But now the challenge will be
10 implementation across the government. I have described a
11 few of DOD's important biodefense programs in written
12 testimony. A few brief words about them here.

13 The Joint Program Executive Office for Chem Bio
14 Preparedness works to accelerate the development of new
15 medical countermeasures. DARPA's Bio Technologies Office
16 runs programs seeking disruptive change in biotechnology,
17 including new ways to manufacture critical molecules and
18 building safety into the work of biological science. And
19 the Biological Threat Reduction program is helping build
20 safe, secure labs in parts of the world where new outbreaks
21 could emerge with efforts in 29 countries. I think all of
22 these programs should be supported.

23 Here are my other recommendations to you. The DOD,
24 together with HHS BARDA should substantially increase
25 efforts aimed at accelerating vaccine and medicine

1 development for new threats. This will require strong
2 programs in government working in close partnership with
3 biopharma.

4 DOD planning assumptions for pandemics should
5 anticipate great disruption to decision-making and
6 operations. The recent Clade X and Event 201 exercises
7 showed how pandemics could affect national decision-making
8 around travel and trade, the use of medical and scientific
9 assets overseas, troop deployments, civil liberties around
10 quarantine, and the national and international allocation of
11 scarce supplies of vaccine.

12 The U.S. Government should reestablish a biological
13 threat assessment process, which used to be in place. It
14 should include not only a focus on bioterrorism, but on
15 state programs as well, as well as the possibility of
16 omnicidal or apocalyptic groups seeking biological weapons.

17 The U.S. Government should plan for the possibility of
18 global catastrophic biological risks. These are events that
19 could lead to sudden widespread disaster beyond the
20 capability of national governments and the private sector to
21 control with potential for great loss of life and disruption
22 of governments, economies, and global security.

23 I would urge you to strongly support the Biological
24 Weapons Convention. It is a critical international norm
25 against the development and use of biological weapons.

1 We should strengthen the U.S. agricultural biodefense
2 planning and programs. The USDA has made substantial
3 progress in recent years around strengthening its programs,
4 but there are priorities that should be addressed, including
5 stronger crop surveillance, animal wildlife surveillance,
6 more support for animal vaccine development, and more
7 funding for ag biodefense overall.

8 We should increase planning with the private sector on
9 biothreat initiatives. The private sector is the maker of
10 vaccines and medicines and diagnostics. It is also the key
11 driver in maintaining travel and trade in major epidemics
12 and in supply chain management, communication channels, and
13 many more essential missions.

14 And finally, we should focus on strengthening the U.S.
15 bioeconomy, which underlies a lot of this. And that
16 includes medicines and vaccines, food production, energy
17 production, and industrial processes. The success of the
18 bioeconomy is important to national security just as in the
19 way that U.S. manufacturing in Silicon Valley have been to
20 U.S. have been to U.S. national security as well.

21 So in conclusion, there are a range of serious
22 biological threats facing the country. It is critical that
23 DOD continue to invest in and prepare for biological
24 threats, particularly high consequence threats, even
25 catastrophic ones, that could have major national security

1 implications.

2 Thank you.

3 [The prepared statement of Dr. Inglesby follows:]

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1 Senator Ernst: Thank you, Dr. Inglesby.
2 Dr. Gerberding, please.

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1 STATEMENT OF DR. JULIE L. GERBERDING, CO-CHAIR,
2 COMMISSION ON STRENGTHENING AMERICA'S HEALTH SECURITY,
3 CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES

4 Dr. Gerberding: Good afternoon and thank you.
5 Chairwoman Ernst, Ranking Member Peters, and all of the
6 staff of the subcommittee, thank you for paying attention to
7 this really important national issue.

8 I am pleased to discuss with the subcommittee the
9 recommendations of a report from the Center for Strategic
10 and International Studies Commission on Strengthening
11 America's Health Security. The full report was released
12 today, and it is entitled "Ending the Cycle of Crisis and
13 Complacency."

14 I co-chair this commission with former Senator Kelly
15 Ayotte. Members of Congress who serve as commissioners
16 include Senators Murray and Young and Representatives Bera,
17 Brooks, Cole, and Eshoo. We also are served by several
18 biosecurity experts from around the country, and their
19 commission work is still ongoing.

20 We began our work with an indisputable premise, and
21 that is that biological threats, whether from natural,
22 intentional, or accidental causes, are occurring more often
23 and have the potential to cause unprecedented harm to
24 Americans and to people around the world.

25 The world we live in now is amazingly insecure,

1 violent, and disordered, and it is exactly in these
2 circumstances that these biologic threats emerge and spread.
3 And all we have to do is look at the DRC situation with
4 Ebola to understand the complexity and the opportunity for
5 emergence.

6 Not only is our disordered world more conducive to the
7 emergence of biothreats, but we are also, of course,
8 increasingly connected and interdependent. Globalization,
9 international trade and travel all mean that an outbreak in
10 one part of the world can very quickly be a threat to us
11 here in the U.S. In other words, a threat anywhere is a
12 threat everywhere.

13 In that context, health security threats truly are
14 national security threats, and that brings them right into
15 the domain of the subcommittee.

16 Unfortunately, despite the fact that policymakers know
17 to invest in threats when they emerge, all too often the
18 recognition occurs only after a health crisis strikes. And
19 I certainly experienced exactly that in my government tenure
20 with the anthrax, SARS, West Nile, avian influenza
21 outbreaks. And my successors at CDC have experienced the
22 same thing with an influenza pandemic, MERS, Ebola, Zika,
23 and so forth.

24 When biothreats are recognized, policymakers do
25 allocate emergency resources, but critical time, sometimes

1 weeks to months, pass before these resources are available,
2 and in that time, lives are lost.

3 Once the crisis fades and public attention subsides,
4 urgency morphs into complacency, investments dry up,
5 attentions shift, and a false sense of security takes hold.

6 So the commission asserts that the U.S. Government has
7 to end this cycle of crisis and then complacency. And we
8 need to replace it with a doctrine that can guarantee
9 continuous prevention, protection, and resilience.

10 In that spirit, we commend the release of the National
11 Biodefense Strategy last fall and the Global Health
12 Security Strategy this year. These do provide a solid
13 foundation, but we need action.

14 So what the commission has presented in its report
15 today is an agenda for specific actions that the Congress
16 might undertake to try and strengthen our ability to be
17 prepared and respond to health security threats.

18 I do not have time to go into all of these. They are
19 outlined in the summary report. But we do have a couple
20 that we wanted to highlight because we think they would be
21 especially germane to the subcommittee.

22 First and foremost, we think it is important that we
23 clarify what leadership at the National Security Council is
24 accountable for the overall government engagement in health
25 security threats. Right now, it is unclear who would be in

1 charge. Strong, coherent leadership at the National
2 Security Council is essential to guaranteeing effective
3 oversight long before crises emerge.

4 We also recommend actions to augment the important role
5 that the Department of Defense plays in health security.
6 One important area is DTRA, and we believe that DTRA should
7 have extended authority to operate in all continents where
8 health security threats exist.

9 Furthermore, the support for the military's infectious
10 disease research laboratories should be strengthened.
11 During my tenure, I had the opportunity I think to visit all
12 of the Navy and Army laboratories around the world, and I
13 saw firsthand how critical they were in the front line of
14 influenza preparedness, but also the broad investment in
15 developing and researching other infections diseases that
16 are not necessarily studied by other agencies or for which
17 countermeasures would not be developed at all. I think
18 these laboratories are a national treasure, a critical front
19 line of our global surveillance and response, and we must
20 continue to support them.

21 The last point I would like to comment on is the
22 importance of our ability to rapidly respond to emerging
23 threats and mitigate harm to affected people. The
24 contingency fund levels for CDC and USAID should be
25 increased and sustained. In addition, we should establish a

1 U.S. global health crisis response corps, which is based on
2 existing CDC and USAID capabilities, but to have this team
3 with the trained and exercised ability to deployed and work
4 with local partners in health crisis settings, even when
5 those settings are insecure.

6 So in summary, the commission urges Congress to invest
7 in biothreat reduction as the national security imperative.
8 We believe the long-term costs of strategic protection and
9 prevention are but a tiny fraction of the astronomic costs
10 of episodic and too often chaotic responses to emerging
11 crises. These smart investments would draw support from
12 all.

13 Thank you for the opportunity to testify. It is really
14 my hope that we can end this cycle of crisis and
15 complacency, and I request that the CSIS report on Ending
16 the Cycle of Crisis and Complacency be submitted for the
17 record. Thank you.

18 [The prepared statement of Dr. Gerberding follows:]
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1 Senator Ernst: Without objection.

2 [The information follows:]

3 [SUBCOMMITTEE INSERT]

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1 Senator Ernst: Dr. O'Toole, thank you.

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1 STATEMENT OF DR. TARA J. O'TOOLE, SENIOR FELLOW AND
2 EXECUTIVE VICE PRESIDENT, IN-Q-TEL

3 Dr. O'Toole: Thank you, Madam Chairman, ranking
4 member, for the invitation to talk about this very important
5 and --

6 Senator Ernst: Do you have your mic on?

7 Dr. O'Toole: Thank you for having me here today and
8 for holding this hearing on this very important, complex,
9 and I think relatively neglected topic.

10 As my two eminent colleagues have described, these
11 biothreats are various, and all of them are quite
12 terrifying. But I would like to suggest a hierarchy of
13 biothreats that is a little different.

14 First of all, we do live in an age of epidemics, and
15 this is not going to change. It is a consequence of trade
16 and travel patterns and the rise of urbanization in
17 situations where people live in conditions of poor
18 sanitation, nutrition, et cetera.

19 Secondly, we have the deliberate bio-attack threats.
20 And bioweapons have been with us a long time, but because of
21 the revolution in biology that is going on, we have the
22 capacity to make new, more powerful bioweapons that could
23 evade all of our capacity to diagnose them and to treat
24 them. And it is very unlikely, given the difficulty of
25 gathering intel on these programs, that we will have advance

1 tactical knowledge of what weapon we might be facing or even
2 where it might come from because I think, as the ranking
3 member said, more and more people are going to have access
4 to this technology as it becomes a foundational technology
5 of the 21st century economy.

6 The third threat and in my mind in some ways worse than
7 the first two is that we will fail to win the economic
8 competition for the biorevolution. And there is no question
9 that we are in a geopolitical competition to wield these new
10 technologies which I believe are going to undergird much of
11 the 21st century economy. And I want to spend most of my
12 time talking about that.

13 We are in the situation today with regard to bioweapons
14 and the threat of bioterror because of the advances that
15 have been made in the life sciences in the past 40 years and
16 the convergence of those advances in biology and
17 biotechnology with digitalization.

18 What we now understand is that biology is programmable.
19 Life runs on code. It is not 1's and 0's. It is nucleic
20 acids that make up the code, but we are beginning -- we are
21 past beginning. We are now able to read, write, and edit
22 that code. And our ability to do so is improving
23 exponentially, faster than Moore's Law.

24 This is going to be phenomenally beneficial. It is
25 going to impact multiple different industries, not just

1 biomed, not just agriculture. And that is because one of
2 the industries that are rising is that of synthetic biology.
3 Organisms are becoming programmable manufacturing systems,
4 and we are already using organisms to make flavors,
5 fragrances, new fabrics, materials with totally previously
6 unknown properties, et cetera. Biology is likely to become
7 the fundamental manufacturing platform of the future.

8 We in the United States are the innovation engine of
9 this new technology, and it is really several families of
10 technologies. But China has said repeatedly and very
11 forcefully -- and they are backing up their words with
12 actions -- that they intend to own the biorevolution. And
13 they are building the infrastructure, the talent pipeline,
14 the regulatory system, and the financial system they need to
15 do that. And that is before we even talk about the secrets
16 and the information and the intellectual property they are
17 stealing from us, which is a small trickle of the
18 contributions that they are building for their own economy.

19 They have good reasons to go after the biorevolution.
20 They have a huge population. They have the highest
21 incidence of cancer on earth. Their population is aging.
22 They are going to need to deal with challenges like
23 Alzheimer's, just as we are, and they have to find an
24 affordable way to deliver health care to their rising middle
25 class.

1 But I do want to note that the United States has not
2 done a good job at translating biology into products. Most
3 of this is happening -- our translational infrastructure for
4 biology is mostly coming from small startup companies in the
5 private sector, which is where In-Q-Tel does its business.
6 Those are the innovation engines for biology and much else.

7 And we need to think about how we would build a more
8 robust infrastructure particularly to manage epidemics,
9 whether they are deliberate or natural. So, for example, we
10 need to have the capacity to, once an epidemic is noted,
11 immediately create diagnostics that could be used like
12 pregnancy tests by the people themselves to determine who is
13 sick and who is not. That would be strategically invaluable
14 in managing the epidemic. We need to be able, as Dr.
15 Inglesby suggested, to rapidly develop a new vaccine in
16 response to an epidemic. We are within reach of
17 technologies that can do that. We need to get much more
18 ambitious as a country in how we are going to prepare for
19 bioattacks and for natural epidemics. But we also need to
20 tend to building infrastructure for securing and promoting
21 the bioeconomy.

22 Thank you.

23 [The prepared statement of Dr. O'Toole follows:]

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1 Senator Ernst: Thank you, Dr. O'Toole. And thank you
2 to our witnesses.

3 We will begin with 5-minute sessions of questioning,
4 and I will go ahead and reserve my time after we get done
5 with our first round here. So I will go ahead and allow
6 Ranking Member Peters to start with questions.

7 Senator Peters: Thank you, Madam Chair.

8 Actually I want to pick up on some of the comments you
9 made, Dr. O'Toole. This question will be for the panel to
10 expand on this.

11 The U.S.-China Economic and Security Review Commission
12 recently released its annual report to Congress, and in that
13 report, the commission highlighted that following the 2001
14 anthrax attacks, the U.S. was reliant on a single foreign
15 source of the active ingredient, doxycycline, which the U.S.
16 sought to treat possible greater exposure to anthrax.

17 In another capacity, I am the ranking member of the
18 Homeland Security Committee, and we are actually in the
19 process right now of drafting a report on our reliance on
20 foreign pharmaceuticals in this country as a national
21 security issue that we need to think about and the fact that
22 in many cases it is 100 percent or 80 percent of critical
23 drugs are manufactured off the shore of the United States.

24 It is my understanding that China is currently the
25 world's largest producer of active pharmaceutical

1 ingredients, known as APIs, which we rely on to make drugs,
2 including those that would treat a biological weapon attack
3 or a pandemic, as you mentioned, Dr. O'Toole.

4 So my question to the panel is, to what extent is the
5 U.S. reliant on foreign services for key drug products and
6 medical supplies such as syringes and needles and other
7 critical medical supplies that we would need to respond to a
8 biological attack today? What is your assessment of that?
9 Dr. O'Toole, if you want to start.

10 Dr. O'Toole: We are critically dependent on China for
11 a lot of drugs, and we have been shipping our manufacturing
12 capacity to Asia for over a decade now. There is not a CEO
13 of a major pharma company who has not been recruited by
14 China to build facilities there.

15 You know, biology is not part of the DNA of the
16 national security community in this country. We have not
17 been paying attention to biology as a national security
18 asset or as a possible threat, and that has to change.

19 The fragility of our supply chain in terms of drugs is
20 a real problem. I would say that we have begun exploring
21 the possibility of using synthetic biology to make these
22 active pharmaceutical ingredients, at least some of them,
23 which I think deserves serious consideration. If there were
24 a natural pandemic in which the entire world needed drugs, I
25 am sure China, as we would, is going to take care of their

1 own people first. We do not have the surge capacity we need
2 even to produce enough of a very common, well used medicine
3 like doxycycline in time to deal with an epidemic.

4 It was also said after H1N1 that if we actually had
5 been able to vaccinate the entire population of the United
6 States with the flu vaccine that we eventually got against
7 H1N1, though it was late for the epidemic, it would have
8 taken 4 years' worth of needles to do that. I mean, we have
9 very insecure supply chains for some of the most critical
10 elements of what would be required medically.

11 Senator Peters: Thank you.

12 Any other panelists like to join in, please?

13 Dr. Gerberding: I will just add that I think our
14 medical supply chain is vulnerable even under everyday
15 circumstances. So, of course, in the context of a global
16 health threat, we would be severely challenged for not just
17 countermeasures but for all kinds of medical products.

18 One area that particularly concerns me is the area of
19 antibiotics because we know we are facing antimicrobial drug
20 resistance on an accelerating scale. CDC just published its
21 update last week outlining the severity of that threat, and
22 we do not have a robust supply of antibiotics today.

23 One of the ways that we do invest to support that
24 potential situation is through the Strategic National
25 Stockpile, which is a very important U.S. asset, and I think

1 it needs to be reexamined in light of the now known
2 realities of market failures and the shortages of the
3 durable goods that we are going to need for any significant
4 threat.

5 Senator Peters: I think it is important when you said
6 we have some challenges right now because we see drug
7 shortages across the board of many drugs that are simply not
8 available, and it forces practitioners to move to a
9 different drug that tends to be a whole lot more expensive,
10 but it may not be any more effective clinically.
11 Antibiotics as well. I understand we have critical
12 shortages in antibiotics today without a biological crisis.
13 You can imagine under a biological crisis, it would be
14 catastrophic. So it is something that we should be focusing
15 on immediately.

16 Dr. Inglesby, would you like to add?

17 Dr. Inglesby: Yes. I would just add that I completely
18 agree with what you have just been saying, and I do think
19 that we treat medicines too much like commodities that can
20 be sourced for the lowest price somewhere in the world. But
21 if we think about medicines we would need in a crisis when
22 every part of the world would be looking for them at the
23 same time, there should be at least a strategic examination
24 of the kinds of things that we must have, and we should
25 consider how we could bring some of those medicines back to

1 the U.S. Obviously, that cannot be done for all medicines.
2 We are a very connected world, but there are some products
3 that are important enough for national security, for public
4 health crisis that we should be thinking about making them
5 here.

6 Senator Peters: Thank you.

7 Senator Ernst: Senator Hawley?

8 Senator Hawley: Thank you, Madam Chair.

9 Dr. O'Toole, let me come back to something you said
10 just a moment ago, that China wants to own the biorevolution
11 I think you said. What steps do you see China taking to
12 succeed in that endeavor?

13 Dr. O'Toole: China has created for itself a -- first
14 of all, they have a very detailed 5-year plan, and
15 biotechnology is in that plan in many different ways.

16 First of all, their goal is to make biotechnology 5
17 percent of their GDP by 2020. They have changed regulations
18 for their own FDA to be more like ours so that they can more
19 easily market to the world. They have created a talent
20 pipeline that incentivizes their own students to go into the
21 life sciences and to bioengineering. They have at least 20
22 different programs, according to the House Oversight
23 Committee, intended to bring scientific talent from the rest
24 of the world, mostly the United States, back to China using
25 very attractive incentives to bring even very senior

1 American scientists back to do research in China.

2 As I said, they have enticed a lot of pharma companies
3 both using incentives, as well as doing a lot of, I will
4 call it, confiscation of IP once they are over and operating
5 in China.

6 They have changed their financial regulations to
7 benefit Chinese biotech companies.

8 They have also -- and this is, I think, important to
9 understand because they have such a long-term well thought-
10 out plan. They are building infrastructure in the form of
11 whole universities, incubators, bio-office parks, primate
12 research facilities, high containment labs very deliberately
13 in order to give themselves the capability of basically
14 being the major biopharma power of the world. But they are
15 not just aiming at biopharma.

16 So we did an examination of their capabilities in
17 synthetic biology. If you map synthetic biology and the
18 different pieces of science and technology that you need to
19 do this to make organisms into manufacturing plants, you
20 will see that the United States is all over the map. We
21 have all kinds of creative companies who are working in all
22 aspects of synthetic biology. If you compare that to China,
23 what they are doing is building from the bottom up, from the
24 fundamental infrastructure up to the more creative parts,
25 and they are doing it at scale. We have nothing like this.

1 And this is something that I know DOD is getting interested
2 in at this point. We ought to encourage that. We ought to
3 take on synthetic biology as a national security priority in
4 view.

5 Senator Hawley: What other defensive measures would
6 you suggest? Or maybe "defensive" is the wrong word. Maybe
7 "proactive" is better. But what measures from a policy
8 perspective would you suggest and recommend that this
9 country take in order to not only prevent China from owning
10 the biorevolution but making sure that we do, for lack of a
11 better expression?

12 Dr. O'Toole: Well, this has been called the Sputnik
13 moment in terms of the biorevolution. And what we did back
14 then worked pretty well. I think taking a look at the
15 National Defense Education Act and really revving up science
16 and technology education in this country -- I would love to
17 do it pre-kindergarten through whatever. But I think we
18 need talent fast. So I would look at incentives to
19 encourage young people to go into biology and biotech, but I
20 would also look at how we get them into government because
21 government really needs more technical expertise than it has
22 easy access to right now. These people have a lot of
23 options in terms of jobs. So that is where I would start,
24 is the talent pipeline.

25 I also would consider making one of the national labs

1 responsible for advancing some of these foundational
2 biotechnologies, particularly the analytical part, the big
3 data part of biology, so that we can strengthen the
4 foundational technologies of genomics, and AI applied to
5 biology is going to be a very big deal. And I could go on,
6 but I do not want to take the whole hearing.

7 Senator Hawley: That is very helpful. Thank you very
8 much.

9 Thank you, Madam Chair.

10 Senator Ernst: Yes. Thank you.

11 And this is a very helpful discussion today. I really
12 do appreciate it.

13 I know there are a number of other committees that
14 might have jurisdiction over these types of topics, whether
15 it is USDA, whether it is Homeland Security. Here in the
16 Senate Armed Services Committee, we have not had a hearing
17 on this topic for 20 years. So, yes, pretty shocking. It
18 is time. It is time to do this. So, again, thank you for
19 doing that.

20 And the reason I get very excited about this and so
21 interested in it is the fact that every time I do meet with
22 different ag commodity groups, in particular our Iowa pork
23 producers, when I am back in Iowa, one of the key concerns
24 that they have is actually how do we secure and protect our
25 livestock against biological threats.

1 And so my question to all of you is, with agriculture
2 being such a significant part of not only our Iowa economy,
3 but also the American heartland, how significant of a threat
4 is there, and what can we do to mitigate that?

5 Dr. Gerberding: I will start by just acknowledging
6 that mother nature is a really good terrorist. China today
7 is experiencing a dreadful outbreak of swine fever that has
8 probably the caused the death or culling of at least 50
9 percent of their entire population of pork, which is the
10 major source of protein for people in China. So this is a
11 major socioeconomic threat to the stability of the state of
12 China today, and that is mother nature.

13 So to my knowledge, every state that has engaged in
14 offensive weapons development has also looked not just at
15 human terrorism or human biologic, but also animal and
16 agricultural biologic capabilities. And we have to assume
17 that that is still an ongoing issue in state-based efforts,
18 not to mention what might be cooked up in the garage of a
19 terrorist somewhere along the way. These are easy things to
20 do. We have very little surveillance and very little
21 capacity in most of the vulnerable places in the world to do
22 anything about it. So I think it is a huge and
23 unrecognized, under-mitigated threat.

24 Senator Ernst: Thank you.

25 Yes, Dr. Inglesby.

1 Dr. Inglesby: Yes. I completely agree with Dr.
2 Gerberding. I would say that the first alarming statistic
3 is that we spend probably about 100 times less on
4 agricultural threats than we do on human threats. I think
5 there are many reasons for this, but one of them includes a
6 kind of a reluctance in the U.S. Government to talk about
7 this threat until quite recently. I think if you go back 5
8 years or 10 years in the interagency discussions around
9 bioterrorism, USDA was not a strong player because USDA has
10 a mission of promoting the food industry, and I think people
11 felt at the time that that was kind of giving mixed messages
12 and concerns and fears. I think that has changed, and I
13 have been impressed with how USDA has been stepping out and
14 really kind of being a serious player in the interagency
15 around the national biodefense strategy development. I
16 think programs are stronger than they were.

17 But still they are small compared to the size of U.S.
18 agriculture, the crops and the herds and the animals around
19 the country. And as Dr. Gerberding said, there are many
20 natural threats that in terms of terrorism, simply moving a
21 natural threat from one place in the world with some simple
22 sample transfer into U.S. herds or crops would be relatively
23 straightforward to do. There is a long list of diseases
24 both for animals and for crops that could cause a terrible
25 impact in our country.

1 And so, in general, I think there needs to be greater
2 emphasis, greater funding for this problem. There is not an
3 integrated risk assessment list for USDA. There are
4 programs that focus on different diseases, but we could
5 raise the entire enterprise by having a more organized list
6 of what the biggest problems are: a stronger national
7 veterinary stockpile, better surveillance programs for crops
8 and wildlife. There are a number of concrete things that
9 can be done, but building on recent successes in USDA -- I
10 think they are showing that they can really step up their
11 programs, but they just need the support of the Congress.

12 Senator Ernst: Yes. Dr. O'Toole, do you have a
13 comment?

14 Dr. O'Toole: I agree this is a big threat. The same
15 forces that are driving natural epidemics are driving
16 epidemics among animals. And what is happening with African
17 swine fever moving around the world is certainly going to
18 happen again and again.

19 What we need to do is the same. We really, really, as
20 a matter of national security, need to get better at
21 managing epidemics. We keep making the same mistakes again
22 and again and again. And the technologies to change this
23 either exist or are within reach. So for animals, we need
24 rapid, cheap, easily manufactured pen-side diagnostics, as
25 they are called, to figure out if pig A is sick and pig is

1 not, as opposed to killing all the pigs within a certain
2 radius of an animal who is diseased. We can get those kinds
3 of options if we are willing to invest in them.

4 In agriculture, one of the advantages is you have a
5 commercial push for these kinds of technologies if the U.S.
6 were to lead some of the basic research that you do not have
7 as easily in human outbreaks where the opportunity costs for
8 the drug companies are so wildly out of sync that they are
9 not going to develop new antibiotics, et cetera, as we have
10 seen. But we can do a much better job at managing animal
11 disease than we are doing now.

12 Senator Ernst: So my message back to Iowa is we can
13 get there. We just need to step it up. Is that right?

14 Dr. Inglesby: Yes.

15 Senator Ernst: Okay. Thank you very much.

16 Ranking Member Peters?

17 Senator Peters: Thank you, Madam Chair.

18 I think I will continue the line of thought by Chairman
19 Ernst, protecting the agricultural industry. Michigan is
20 also a big agricultural State, in fact, the second most
21 diverse agricultural State next to California, with all
22 sorts of crops. And as ranking on Homeland Security, we
23 just -- I authored a bill to increase our agricultural
24 inspectors at the border, which is critically important to
25 protect that industry, as well as public health. We are

1 understaffed when it comes to agricultural inspectors. We
2 will hopefully change that if the House acts on the bill
3 that we just passed out of the Senate. Not only human
4 inspectors but probably the most sophisticated tool you can
5 use, which are canine teams. Sophisticated noses of dogs is
6 pretty amazing as to what they can pick as things are
7 crossing the border.

8 So my question is -- and especially, Dr. Inglesby, you
9 are talking about how we need to do more -- I will get the
10 assessment of the panel. What sort of coordination is going
11 on between USDA, the Department of Defense, the CBP, or
12 Homeland Security folks? We have to be able to identify
13 where some of these outbreaks are around the world, alert
14 folks here who are on the border protecting us. We have got
15 to have a real coordinated system. What is your assessment
16 of how coordinated that is? And do we need to do a lot
17 more, and what would be your advice? Whoever would like to
18 start. I would love to have all your thoughts.

19 Dr. O'Toole: Well, I will start.

20 I spent 5 years in Homeland Security. People do try to
21 coordinate, but they do not have the tools they need to make
22 this a very reassuring process.

23 Without the technology -- dogs are great. Love dogs,
24 have one. It is really hard to --

25 Senator Peters: We need more than dogs you are saying.

1 [Laughter.]

2 Dr. O'Toole: We really need more than dogs.

3 Senator Peters: But they are great.

4 Dr. O'Toole: They are good for some things. It is
5 very difficult to quantitate how good they are or whether
6 the dog is having a bad day. So they are great as a first
7 line of defense. They are not very reassuring as the line
8 of defense.

9 But CBP, for example -- if you go to a port and you see
10 what CBP is faced with day after day in terms of trying to
11 figure out whether exotic pests are coming in, a big threat
12 to agriculture, for example, they actually disassemble
13 trucks, loaded trucks, and go through them box by box,
14 packing straw by packing straw to find bugs and then compare
15 them to the charts on the wall, what bug is this. We need
16 more technology to do this more effectively. That is all
17 there is to it.

18 So I think people are trying to coordinate amongst the
19 agencies. I do not think they have the tools that they
20 want. I agree with Dr. Inglesby. Agriculture has been late
21 to the table. They need a much bigger research budget. I
22 do not think you can do much about that from this committee.
23 But again, we are under-investing in these areas in terms of
24 R&D and the translational science that has to come out of
25 it. These things now are in the arena of national security.

1 Senator Peters: Does anybody else want to add?

2 Dr. Inglesby: Yes. I would just add just a couple of
3 sentences.

4 I would say one very encouraging thing was when the
5 National Biodefense Strategy was getting developed in the
6 lead up to 2018 fall, there were four agencies that were co-
7 conspirators or co-leads on the effort, and USDA was one of
8 them, alongside DHS, HHS, and the Department of Defense.
9 That was surprising to many people in the field because USDA
10 had been kind invisible before. So that was a sign of them
11 really being either pulled or stepping up into the
12 interagency. They are part of an integrated lab network
13 that looks at CBRN threats alongside HHS and EPA
14 laboratories. So there is some kind of interaction there.
15 They definitely do engage internationally with the Food and
16 Agriculture Organization, which is the big organization
17 around food safety in the world. So I think there is some
18 interaction, but I completely agree with Dr. O'Toole that
19 they are on the rise, but they are still kind of starting
20 from a lower position in terms of research and budget.

21 Dr. Gerberding: I would just add a very small but
22 important perspective, and that is the vast majority of the
23 new or reemerging infectious diseases that are being evolved
24 naturally are zoonotic diseases, meaning they arise from
25 animals. And so the criticality of the integration between

1 USDA and the CDC for infectious disease surveillance and
2 adding into that the EPA because some of these diseases also
3 involve the ecosystem -- we really need a one-health
4 approach to understanding emergence. And again, the
5 technologies are sorely lacking because there is not an
6 investment in that kind of not just interagency but
7 interdisciplinary research and tech translation.

8 Senator Peters: It is clear we need a whole-of-
9 government approach here, and we are far from actually doing
10 that now. So I think that is certainly a big takeaway from
11 that exchange from you, which I appreciate.

12 I was just at the Detroit Metropolitan Airport seeing a
13 demonstration of those dogs and others.

14 But the one thing that was particularly concerning to
15 me is the amount of actual biological material and viruses
16 and others that are coming across. The people who are
17 researchers -- they are bringing all sorts of agents in,
18 which they should not. In fact, I understand half of all
19 the biological material that is stopped at the border is at
20 Detroit Metropolitan Airport. And I said is it because it
21 is Detroit or because you are really good at it. The answer
22 was probably a little bit of both. But it is concerning as
23 to what are we not stopping. For whatever we stop, I am
24 sure there is a lot that is getting through, which is why
25 this is so critical that we put that together.

1 If I may, I am a little over time, Madam Chair. If I
2 may just ask another question.

3 Dr. Gerberding, you mentioned the study, the Cycle of
4 Crisis and Complacency. And in your testimony here today as
5 well, your oral testimony, you talked about where pandemics
6 are occurring or where they start -- the outbreaks are
7 occurring around the world -- they are usually places of
8 great disorder, a lot of things happening there. The
9 security issues are incredibly challenging where they come
10 from. The Ebola outbreak in Congo is an example of that
11 occurring in a place with regional conflict.

12 In 2014, in the Ebola outbreak, the United States was
13 able to deploy upwards of three -- a real massive, kind of a
14 heavy lift of folks to help deal with that situation. 3,000
15 combat engineers, mobile hospitals, and marshaled a combined
16 team of medical professionals from the Army, the Navy, the
17 Public Health Service. Actually the Michigan National Guard
18 was engaged in Liberia, our partnership state there. We had
19 a number of our guards people there that forward deployed as
20 well.

21 So my question to you is to what extent do you think
22 the DOD, when responding to these issues, really has to be
23 doing more than just providing medical services? They are
24 going actually have to stabilize a region. That is a
25 broader mission than we normally think about when we are

1 dealing with a potential outbreak of a pandemic, and yet the
2 consequences of not containing that pandemic can be
3 catastrophic. How do we square all that, and how should we
4 think about deploying DOD assets in these kinds of
5 emergencies?

6 Dr. Gerberding: I think it is a very complicated set
7 of issues. In the case that you cited in Liberia, our
8 military was welcomed into the environment, and the mission
9 there was primarily logistics, building infrastructure to
10 support the relief efforts that were ongoing, hospitals,
11 infrastructure, et cetera. And our Department of Defense is
12 accustomed to providing that kind of humanitarian logistic
13 support in all sorts of natural disasters, et cetera.

14 But we were not there to provide security. And
15 generally, we would like to think that the UN security
16 forces or the local governments would have that
17 responsibility, but as we have seen in the DRC, that is not
18 always the case nor is it always successful. So I think
19 that challenges the role of the Defense Department in
20 providing the security when the threat in one region could
21 extend to be much broader or a threat to the United States.
22 So I think that is an area where we need a lot of strategic
23 policy work on an ongoing basis.

24 The other side of the coin and part of the reason why
25 the commission report recommends the development of this

1 ready corps is because we need to bring a certain kind of
2 technical expertise, which is not the military's forte, but
3 the surveillance, the epidemiology, the tech transfer, the
4 diagnostics, et cetera, et cetera, that we need deployable
5 troops who are trained to be able to go in and instigate
6 those capabilities in environments that are not
7 intrinsically secure. And we do not have that capability
8 right now. That is why it has been so challenging for the
9 CDC, for example, to be in the DRC because we do not have
10 the security context and we do not really have that kind of
11 deployable, well trained, well exercised unit to serve in
12 that sort of environment. It is an unmet need and one that
13 I hope we would really put a higher priority on addressing
14 going forward.

15 Senator Peters: Thank you.

16 Dr. Inglesby: I would maybe just add a comment.

17 Senator Peters: Yes, please.

18 Dr. Inglesby: In the West Africa Ebola response in
19 2014-2015, in my view and I think the view of many, it
20 really was a threshold moment when the President decided
21 that the Department of Defense would become fully engaged in
22 the operations around response. DOD did not send doctors
23 and nurses, but they sent heavy lift. They sent their ship.
24 They started building things. They already had laboratories
25 there that were working on diagnostics. And so that was a

1 real threshold moment.

2 And I think in the aftermath of that, as people have
3 reviewed the DOD experience in West Africa, there still is a
4 tension within the Department of Defense about the extent to
5 which the Department of Defense should be involved in
6 foreign operations around infectious disease crises. In my
7 view, they are indispensable in terms of operations. If you
8 really want something to be done by the U.S. Government, DOD
9 has by far the most operational capacity, and there are
10 going to be moments to do that. But I understand that in
11 DOD leadership in the command leadership, that there is
12 reluctance to have doctors and nurses, in particular,
13 involved because of the way that it will affect overall
14 operations.

15 So I think it is an open issue. I would urge the DOD
16 to be involved in those kinds of operations, but I do not
17 believe it is resolved within the strategy.

18 And the second thing I would say, just to echo Dr.
19 Gerberding, is that in the current DRC Ebola response, the
20 CDC has been indispensable in the last 20 Ebola responses
21 since Ebola was discovered. In this response, they were
22 held back by the U.S. Government for safety and security
23 reasons because we had no way for the U.S. Government to
24 determine that there was no safe way to have them in the
25 field for a long period of time. That is beginning to

1 change.

2 But it does show that we will need in the future, since
3 more and more outbreaks are happening in disordered, broken
4 places in the world where things could spiral, get a
5 foothold and then create chaos in the region -- we are going
6 to need, as Dr. Gerberding said, ways to operate in unsafe
7 environments, ways to have our scientists and experts and
8 public health officials be in places where outbreaks are out
9 of control even if they are unsafe. So I do think it is an
10 important issue that we have not really resolved.

11 Senator Peters: And probably new specialized units
12 that are specifically trained for that.

13 Dr. Inglesby: Yes. Units that are part of that that
14 are on the DOD side, units on the CDC side, scientific side.
15 I think they will need to be able to work together in ways
16 we have not sorted out.

17 Senator Peters: Thank you.

18 Dr. O'Toole: May I comment on that?

19 Senator Peters: Yes.

20 Dr. O'Toole: I am all for training the special units,
21 but I think the situation on the ground is going to outrun
22 even the U.S. Government's ability to take care of it unless
23 we have better technologies. We are much better off trying
24 to figure out how we could make vaccines on demand and then
25 distributing those than we are sending thousands of members

1 of the armed services just to quell disorder. We have to
2 get a strategic approach to epidemics that has got to look
3 very different from what we are doing now. And I think
4 technology is the way through. Because of the
5 biorevolution, there are possibilities out there that we
6 could make good on if we invested in them.

7 Senator Ernst: Thank you, Dr. O'Toole.

8 I want to continue on a little bit with some of that
9 technology. You had mentioned that the integration of
10 artificial intelligence is important in staying ahead of
11 various biothreats. And so if we can just discuss that
12 briefly, I think that would be very helpful for me. Can you
13 elaborate on how this type of technology would impact both
14 the potential offensive and defensive applications with
15 respect to biotech?

16 Dr. O'Toole: So artificial intelligence of different
17 kinds, machine learning, deep neural networks, and so forth,
18 is already being used, for example, in drug discovery to
19 hasten drug discovery. It is being used in medical imaging
20 and in digital health in many different ways. But it is
21 going to have, I think, the greatest near-term impact in
22 biology on these foundational technologies, on genomics and
23 synthetic biology in particular.

24 If you think of genomics as you are trying read a code
25 of a single genome -- and today we are trying to understand

1 what a particular gene does by comparing it to many genomes
2 and trying to figure out this person is sick because that
3 gene there is missing, to take a simple case. In that case,
4 the bigger your library, the more genomes you have sequenced
5 and put into a library that keeps things accurate and easy
6 to access, you are advantaged. What AI is going to do is
7 not only make it faster to sequence genomes, but they will
8 be done so more accurately. Google has already done this
9 and shown one way to do it, mostly using machine vision.

10 What you then want to know is you want to understand
11 how to read and write the genome once it is sequenced. And
12 what AI allows you to do is intelligently go through all of
13 these multitudinous possibilities much faster and more
14 accurately. And then you can iterate on it.

15 So it is going to improve sequencing. It is going to
16 improve DNA synthesis, and it is going to improve DNA
17 editing. And there are already basic science experiments
18 going on in all those fields.

19 China, for example, has of course a philosophy that the
20 state and the private sector are one and the same. The
21 military and the private sector are one and the same. And
22 they have combined their big Internet giants, Alibaba,
23 Tencent, and so forth with their biotech companies. So
24 Alibaba is investing in biotech. Tencent is helping BGI,
25 Beijing Genomics, Inc., with their sequencing problems. And

1 they have recognized and are industrializing this
2 combination of AI and biotech. It is mostly going to be
3 beneficial. It is going to help us get new medicines
4 faster. It is going to help us understand toxicity earlier.
5 It is going to create whole new realms of products that we
6 have not imagined yet. But they, as I said, are
7 institutionalizing it. We are experimenting with it.

8 Senator Ernst: I appreciate that. And again, we need
9 to step up in this area and find those solutions.

10 So your estimation -- and I am drawing from that that
11 there is a lot of work that we need to do. But how well
12 postured is the Department of Defense in leveraging AI in a
13 biodefense strategy?

14 Dr. O'Toole: I do not think they have thought about it
15 yet.

16 Senator Ernst: I would probably agree with that
17 assessment.

18 Anybody else care to comment on that?

19 [No response.]

20 Senator Ernst: And, Dr. Gerberding, if we could go
21 back a little bit. We were just talking about the
22 collaboration between different governmental agencies. And
23 the Health Security Commission report released today by CSIS
24 recommends restoring health security leadership at the White
25 House National Security Council. And when was this position

1 established? And then why was it eliminated?

2 Dr. Gerberding: So in my experience in the context of
3 some of the most difficult and threatening infectious
4 disease outbreaks, inevitably someone is pulled to be the
5 czar of the occasion for that particular situation. But in
6 2016, the White House did appoint a senior White House
7 official reporting through the National Security Council to
8 be responsible for a directorate that was charged with the
9 preparedness and response to biologic threats. That
10 directorate was established. It began its work, and then in
11 2017 it was disbanded. So I do not know why it was
12 disbanded. I think there were lots of changes. The
13 administration changed and so forth. But I think the
14 mentality often has been that these are important during a
15 crisis, but the need for them dissipates once the acuity of
16 the crisis has subsided.

17 Senator Ernst: But the recommendation would be that it
18 needs to be a consistent, stable position within the
19 National Security Council.

20 Dr. Gerberding: It has been an essential role for
21 cross-government collaboration in every single infectious
22 disease situation I have ever observed.

23 Senator Ernst: And do you believe then having that
24 position in place, that person would be able to assist maybe
25 in orchestrating the breakdown of various silos that exist

1 between agencies?

2 Dr. Gerberding: That would be a primary function, and
3 that applies both to the planning and strategy that we have
4 been talking about is missing across a number of our
5 agencies, but also in the actual operations and in the
6 aftermath. So it is a continuous cycle, and it needs that
7 constant strategic, iterative improvement over long arcs of
8 time.

9 Senator Ernst: Okay. We are going to go ahead.
10 Senator Peters will have just a couple more questions.

11 Senator Peters: Thank you, Madam Chairman.

12 Dr. Gerberding, this was in your report as well. As
13 you know, the Department has used the Cooperative Threat
14 Reduction program, which is also known as the Nunn-Lugar
15 program, for the past 20 years to help us reduce some of the
16 danger of biothreats in the United States. The program
17 started out in the former Soviet Union to secure bioweapons
18 stockpiles in their program, but we have continued to use
19 that program. And your study specifically calls out this
20 program as something that should be protected and sustained.
21 Dr. Inglesby, I know you were involved in that as well.

22 So my question to you is what should the CTR program
23 focus on in the future with respect to securing biological
24 threats that could harm the United States in your
25 estimation. If both of you could answer that and, Dr.

1 O'Toole, if you want to jump in too.

2 Dr. Gerberding: Yes. I will start.

3 I had an introduction to this capability a number of
4 years ago when there was an outbreak of plague in one of the
5 countries that was formerly a part of the USSR. So the
6 question was, the plague that we were observing in animals
7 was actually a sign that there was some offensive weapon
8 development and deploying going on, and that resulted in an
9 investigation comparing biologic fingerprints and so on and
10 so forth. So it revealed to me how important this effort
11 was to provide resources and support for scientists to
12 redeploy their technical capabilities in constructive
13 directions and so forth. And since that time, this has come
14 up in a number of other areas of the world.

15 So my own opinion is this is an extremely important
16 methodology for repurposing scientific know-how and acumen,
17 but also harnessing that expertise in ways that truly can
18 hopefully transition into more constructive biotechnology
19 solutions. So I see it as a high priority for continuation,
20 and I would look forward to Tom's view because I know we
21 have had this conversation before.

22 Dr. Inglesby: Yes. I also think it is quite a
23 valuable program, and I think it is a place in the
24 government that helps other labs and research facilities in
25 the world develop biosafety practices and biosecurity

1 practices that increase the chance that pathogens will stay
2 safe in their refrigerators and not walk out with people or
3 not be susceptible to theft or diversion.

4 I think they also do a lot of important training
5 programs to try and train trainers in different parts of the
6 world. I know that CTR BTRP, the bioprogram in CTR,
7 recently had a training program in North Africa which
8 trained biosafety and biosecurity leaders from a variety of
9 North African countries in the context of violent extremist
10 organizations trying to kind of think about the overlap
11 between terrorism and potential diversion of samples. And I
12 think that is the kind of thing that they do very well. I
13 think they are in nearly 30 countries, 29 countries in the
14 world, and are doing things that other parts of the
15 government are not doing.

16 They also are trying to help build surveillance
17 systems. That is obviously not their only -- I mean, there
18 are many other agencies, especially CDC that does a lot of
19 very critical disease surveillance. I think with their
20 relationships that they have established in laboratories,
21 they can be helpful to that larger mission.

22 Senator Peters: Dr. O'Toole, my last question to you,
23 just to pick up on what you were you talking about with the
24 advances in synthetic biology and CRISPR, all these new
25 technologies that are going to change the world

1 dramatically. It is an exciting time to live, but it is
2 also a scary time to live at the same time.

3 My question to you is that whenever you are dealing
4 with advanced research in biology, it can often raise a
5 whole host of moral and ethical issues that need to be
6 addressed. And given the value system that we have in this
7 country, we want to adhere to that at every step possible.
8 However, other countries may have a different set of moral
9 and ethical principles. How do you see those different
10 principles in terms of biological research? How do you
11 think about that? Is that a concern for you? As a
12 committee, how should we be thinking about countries that
13 are not going to be constrained in the same way we are
14 likely to be constrained in this country when it comes to
15 biomedical research?

16 Dr. O'Toole: This is an area of profound questions
17 that I think have to be approached very carefully and very
18 seriously. We will be disadvantaged compared to China in
19 some areas of biology, stem cells for example, because they
20 are moving forward faster than we are. In the end, they may
21 make more mistakes and we may get to the happy place sooner.
22 As a physician, I believe very strongly in doing everything
23 we can to avoid doing harm. Science is very empirical.
24 Sometimes you make mistakes and you have to pull back and
25 think again. So I think this is going to be a knotty

1 problem that deserves very sustained, high-level attention.

2 When we started the human genome project in this
3 country, we built in the funding for the project money to
4 pay for research in ethics. And I would recommend that we
5 do the same thing again for synthetic biology, for gene
6 engineering, and so forth. What it did was it laid the
7 groundwork for a national dialogue, which I think was
8 extremely constructive. And all of the anxiety and true
9 fear that popped up when we first started doing recombinant
10 DNA back in the 1970s has proved not to have led to a
11 terrible tragedy I think partly because we moved very
12 thoughtfully forward. We have to create the foundation and
13 the infrastructure for doing that again for these sciences.

14 I would say about China, though, that they are in a
15 terrible place vis-a-vis the health of their population.
16 The reason they are moving forward so aggressively is that
17 they are desperate for progress. And when you look at the
18 opinions of the Chinese people, they are much more
19 acceptable of risk than I think Americans are in this realm.
20 They are very interested in new technologies that they think
21 could help cure disease, change birth defects, et cetera, et
22 cetera. So I do not read the gene-edited baby episode as
23 China being negligent so much as I think it is a more
24 nuanced view of that particular situation is warranted on
25 our part. They have terrible problems that they are trying

1 to fix, and that is part of their appetite for risk.

2 Senator Peters: Thank you.

3 Dr. Inglesby?

4 Dr. Inglesby: Yes. I would just certainly agree. I
5 would just add that the U.S. has had the opportunity to set
6 standards in the world around science for a generation, and
7 often when the U.S., especially in the world of science, the
8 NIH, in partnership with other agencies, has taken positions
9 or the recombinant DNA conference back in the 1970s which
10 helped set standards for how to manage recombinant DNA
11 science -- I think those things do have a chance of taking
12 hold elsewhere in the world. So the more that we can kind
13 of promulgate and seek partnerships around this, I think it
14 is real. I think it can help.

15 I am particularly worried about a very small realm of
16 science, which has emerged in the last few years, which is
17 science intending to create very pathogenic strains of
18 pathogens. I think we have not taken the position we took
19 in other kinds of technologies like gene editing or
20 recombinant DNA science. We have actually gone in the other
21 direction. We have been, I think, way in front of our
22 headlights, and other countries are observing how we are
23 operating and how we are funding that science. So I think
24 there are things that we could do in our own governance of
25 science which would be, I think, a little bit more

1 responsible. But generally speaking, I think the U.S. is
2 able to help set some standards that other people pay
3 attention to.

4 I know China, just to speak about China -- there was a
5 meeting this summer where a number of Chinese scientists
6 came over to talk about the gene-edited baby experience. I
7 think there are many leading scientists in China who were
8 shocked and appalled about how that all happened. I think
9 they certainly have to think about their disease risks in
10 their population, but they are also worried about how
11 scientists kind of got out in front of their scientific
12 establishment. So I do not think it is a homogenous
13 national reaction to gene editing. I think there are
14 proponents of it, and there are people who are worried about
15 it as well, even in China.

16 Senator Peters: Thank you. I appreciate it.

17 Senator Ernst: And I am going to wrap up the hearing
18 with just a quick question, and all of you can participate
19 in this. In your view -- I am going to give you the big
20 four that we have. Near peer adversaries -- but what is the
21 current estimate of biological warfare capabilities? So,
22 for example, the range of delivery, extent of biological
23 weapons available, amount of biological weapons, so on and
24 so forth. Low, moderate, or high for North Korea. What
25 would your assessment be of North Korea and their biological

1 capabilities? It is a fun little exercise. Very
2 enlightening.

3 Dr. O'Toole: I think every country in the world has
4 the capability of delivering a devastating biological
5 weapon, North Korea included. I think they are probably
6 more intent on it. It is very difficult to collect intel
7 out of North Korea. There are indications that they have a
8 BW program. And beyond that, we would have to be in a
9 classified space.

10 Senator Ernst: Absolutely.

11 Dr. Gerberding: I would just say it behooves us to
12 assume they do, whether we have evidence to back that up or
13 not. I think it is more likely than not.

14 But I would also just like to say one more time the
15 best terrorist of all is mother nature.

16 Senator Ernst: Yes, Dr. O'Toole.

17 Dr. O'Toole: So that gets said a lot, and I think it
18 is no longer true. I think we have to understand that the
19 capacity to build new, very powerful, very, for want of a
20 better word, sneaky biological weapons has been unleashed,
21 and it is widely accessible. And we have got to start
22 thinking about this in a national security context.

23 Senator Ernst: Can we say that is probably true then
24 of North Korea, Russia, China, Iran?

25 Dr. O'Toole: Yes.

1 Senator Ernst: Dr. Inglesby?

2 Dr. Inglesby: I agree that any country with any kind
3 of industrial capability, any kind of basic science program,
4 which is almost all countries on the planet, if they chose
5 to make biological weapons, they would succeed. There are
6 not any technical barriers that would prevent a country from
7 doing that.

8 I think what is really useful at the moment is that we
9 have a Biological Weapons Convention, which creates a very,
10 very strong taboo against it, an international pariah status
11 if you are caught making biological weapons. It is not a
12 perfect treaty, and there are obviously countries that have
13 cheated on it. But it is a helpful norm given that any
14 country could certainly step up and develop and use
15 biological weapons if they chose.

16 Senator Ernst: Very good.

17 And on that happy note, I think we will go ahead and
18 wrap up this hearing this afternoon. And I do appreciate
19 the input that has come from our panel of experts in this
20 topic. And it underscores the fact that we as the United
21 States Government, as DOD, also need to truly step up what
22 we are doing on biological warfare preparedness, as well as
23 making sure that we are breaking down those silos that exist
24 between DOD and maybe all of the other agencies that are
25 working in these areas as well.

1 And with that, I want to thank you once again for
2 joining us today.

3 And this will conclude our Emerging Threats and
4 Capabilities hearing.

5 [Whereupon, at 4:17 p.m., the hearing was adjourned.]

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