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Before the

Subcommittee on Personnel

COMMITTEE ON
ARMED SERVICES

UNITED STATES SENATE

HEARING TO RECEIVE TESTIMONY ON THE DEPARTMENT OF
DEFENSE'S EFFORTS TO ENSURE SERVICEMEMBERS' ACCESS
TO SAFE, HIGH-QUALITY PHARMACEUTICALS

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4
5 Tuesday, April 30, 2024

6
7 U.S. Senate
8 Committee on Armed Services
9 Subcommittee on Personnel
10 Washington, D.C.

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12 The subcommittee met, pursuant to notice, at 2:30 p.m.
13 in Room SR-232A, Russell Senate Office Building, Hon.
14 Elizabeth Warren, chairman of the subcommittee, presiding.

15 Committee Members Present: Warren [presiding], Kaine,
16 and Scott.

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1 OPENING STATEMENT OF HON. ELIZABETH WARREN, U.S.
2 SENATOR FROM MASSACHUSETTS

3 Senator Warren: This hearing will come to order.

4 We welcome everyone to today's hearing to receive
5 testimony on the efforts of the Department of Defense to
6 ensure servicemembers' access to prescription drugs that are
7 safe, high quality, and effective.

8 We owe our servicemembers and their families the best
9 possible health care. This is a morale issue, it is a
10 recruiting issue, and ultimately, it is a national security
11 issue.

12 DoD spends about \$5 billion every year on
13 pharmaceuticals. That is about 2 percent of the entire U.S.
14 commercial pharmaceutical market. Now to make these
15 purchases, DoD must navigate many of the same challenges as
16 civilian health systems.

17 For example, according to the FDA, almost half of the
18 drugs on DoD's operational medicines list -- a list that
19 contains drugs necessary for warfighting that are essential
20 for meeting the medical needs of servicemembers -- about
21 half those drugs are in shortage. This includes the blood
22 thinner heparin, a common anesthesia drug called midazolam,
23 and morphine for pain management. The impact of these drug
24 shortages can be devastating. A shortage could mean using a
25 drug with worse side effects, or it could mean having to use

1 the second- or third-line treatment for an illness, rather
2 than the treatment that is most effective.

3 While there are many factors that can cause shortages
4 from spikes in demand to natural disasters to inspection
5 failures -- most drugs in shortage share a common feature:
6 they are generics. That means they are no longer protected
7 by patents, and they can be made by any manufacturer with
8 approval from the FDA. Despite this, most generic drugs
9 have very little competition. In fact, 40 percent of the
10 generic drugs sold in the United States have just one
11 manufacturer.

12 Why? Because the profit margin for some generic drugs
13 is so low that American manufacturers just are not
14 interested in making them. As a result, more of DoD's
15 generic drug supply is coming from foreign manufacturers who
16 can produce the drugs at even lower costs.

17 DoD's reliance on overseas manufacturers is not limited
18 to finished drug products. The ingredients used to make the
19 medicines, called active pharmaceutical ingredients, or
20 APIs, and the ingredients used to make APIs, known as key
21 starting materials, or KSMs, are also increasingly sourced
22 from abroad.

23 The COVID-19 pandemic exposed the risks we face by
24 importing more and more of our commercial drug supply
25 overall. DoD relies on those imported drugs and that gives

1 potential adversaries the power to restrict DoD's access,
2 which can result in harm to our servicemembers, to their
3 families, and to our national security. In addition, the
4 U.S. has less and less visibility into and oversight of
5 foreign manufacturers and their manufacturing practices, and
6 that is particularly true with China.

7 These problems have concerned me for a long time, and
8 that is why I partnered with Senator Rubio to secure
9 language in the fiscal year 2023 NDAA requiring DoD to
10 develop guidance for risk management of the Department's
11 pharmaceutical supply chain, to report on supply chain
12 vulnerabilities, and to establish a working group to develop
13 policies for allocating scarce pharmaceutical resources.

14 When a drug does not work properly it can have serious
15 consequences for servicemembers. Bloomberg reported last
16 year that an outside lab tested tacrolimus, an
17 immunosuppressant used to treat soldiers who have lost limbs
18 in combat. The results revealed that some generic versions
19 of the drug might not work. Worse yet, they could cause
20 kidney failure or seizures.

21 So last summer, in accordance with Senator Rubio's and
22 my provision, DoD entered into a cooperative agreement with
23 an independent lab to conduct a pilot study to test the
24 quality of 12 finished drugs in the military drug supply.
25 And in November, DoD revealed that 27 percent of the drugs

1 on the FDA's Essential Medicines List are at, quote, "Very
2 High Risk" because they are either dependent on Chinese
3 manufacturers using Chinese ingredients or were derived from
4 unknown sources.

5 So we are holding this hearing today to learn more
6 about these challenges and to discuss DoD's capacity to
7 address them.

8 I want to thank Ranking Member Scott for his commitment
9 to improve the quality of life for our servicemembers and
10 for their families. And to our witnesses, I say welcome and
11 thank you for appearing today.

12 We will have two panels. The first panel consists of
13 officials from the Department of Defense who will explain
14 how DoD is currently addressing drug shortages and DoD's
15 existing capabilities for biomedical research and
16 development. I am pleased to have the opportunity to
17 introduce them, which I will do in just a minute, but I want
18 to see if Senator Scott has any remarks he would like to
19 make first.

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1 STATEMENT OF HON. RICK SCOTT, U.S. SENATOR FROM
2 FLORIDA

3 Senator Scott: Sure. First I want to thank Chair
4 Warren for doing this. I think this is a very important
5 issue. I think any of us that would have a health issue, we
6 would want to make that our kids and our grandkids, that
7 they had the best medicine out there. And it sure does not
8 seem like we are doing that.

9 For several years I have raised concerns over the
10 pharmaceutical supply chain in this country. The COVID
11 pandemic exposed the vulnerabilities in our supply chains
12 and the dangers of continuing to be reliant on Communist
13 China for medicines and other critical products. I do not
14 know if anybody, logically, would ever want to be dependent
15 on Communist China for anything.

16 While the pandemic is over, these problems continue.
17 America is far too dependent on Communist China and other
18 foreign producers, and our supply chains will be massively
19 disrupted when Xi decides to invade Taiwan. I do not think
20 it is a question of if. I think it is a question of when.

21 If we do not take action to fix this now, the supply
22 chain disruption that will occur when Communist China
23 strikes Taiwan will be extreme and cause unbearable pain for
24 the United States and every American family. No one will be
25 safe from the impact of supply chain disruption if we

1 continue down our current path. Prices will skyrocket even
2 higher; product shortages will be widespread and severe. I
3 mean, I just cannot imagine that we are buying essential
4 items like medicines, technology, household goods, you name
5 it. Everything is going to be affected, and I do not know
6 why we buy anything from Communist China.

7 But today we want to focus on medicine and the
8 pharmaceutical supply chains that our military depends on.
9 I am glad we have this opportunity to discuss how
10 pharmaceutical safety, quality, and supply chain issues
11 affect our warfighters. I think we all agree that America's
12 dependence on Communist China and other foreign producers
13 for medicines is a significant problem, and it does not
14 appear to being addressed.

15 I have been fighting for legislation to get this fixed.
16 My American Drugs Act will create a strong incentive for
17 companies to invest in domestic pharmaceutical production,
18 address the ongoing drug shortages, and work to prevent
19 future ones, and shift away from reliance on Communist
20 China. The American Drugs Act seeks to fix this problem by
21 leveraging the buying power of the Federal Government and
22 requiring Federal health programs to purchase American-
23 manufactured generic drugs if there are two or more
24 manufacturers of a generic drug. I think this bill is
25 needed, given the issues we face today, and as the Chair

1 said, it is not a little bit of money that our defense
2 industry is buying. It is billions of dollars every year.

3 The Department of Defense recently conducted a
4 pharmaceutical supply chain study, as required by 860 of the
5 fiscal year 2020 National Defense Authorization Act, and I
6 want to thank Chair Warren for leading that effort. This
7 study revealed the Department has a high dependence on
8 foreign material and foreign trade agreements to maintain
9 current pharmaceutical capabilities. I do not know anybody
10 in their right mind who trusts anything made in China. The
11 report shows that 54 percent of the pharmaceutical
12 ingredients that encompassed the products on the FDA's
13 Essential Medicines List, being the critical pharmaceuticals
14 that the Department should have access to, are from sources
15 that are at a high risk of disruption. Who would do that?
16 Only a quarter of the drugs on the list have domestic
17 manufacturers.

18 As I mentioned earlier, during COVID we learned the
19 hard way that relying on non-allied countries for our
20 medical supply chain poses a real danger. For that reason
21 it is imperative that we work to ensure DoD's supply chains
22 are independent from non-allied nations for necessary
23 pharmaceutical treatments. In the future these supply
24 chains could easily cease to exist, and I assume they will
25 when China invades Taiwan.

1 I am also working on legislation that would have the
2 DoD work with manufacturers to build up our domestic
3 pharmaceutical manufacturing base. If we have a drug
4 shortage of antibiotics, where about 90 percent of the key
5 inputs to make those drugs come from China, it becomes a
6 readiness issue because our strength comes from a ready and
7 health warfighter.

8 About 90 percent of the drugs dispensed at the pharmacy
9 are generic drugs, but a country like China-controlled
10 generic drug manufacturing makes us more dependent as we
11 ramp up for possible conflict.

12 Today I look forward to hearing from both the Defense
13 Logistics Agency and the Department of Defense Health Agency
14 to discuss the findings of the Department's pharmaceutical
15 supply chain study and their ongoing work to study and
16 secure these supply chains.

17 In addition to focusing on pharmaceutical supply
18 chains' security we must address the specific medical
19 countermeasure needs of the warfighter. The Walter Reed
20 Army Institute of Research has a Pilot Bioproduction
21 Facility that can aid the transition phase from research and
22 development to early-stage clinical trials for warfighter-
23 specific vaccines and biologics. While this effort is small
24 in scale, it is important that we discuss the success that
25 General Bailey and his team have found in keeping our

1 warfighter healthy and combat ready.

2 History shows us that infectious diseases have a high
3 morbidity rate in theaters of war. As we look towards the
4 pacing threat in the Pacific I would like to understand the
5 medical challenges that our troops will face, what
6 innovative tools and improve medical countermeasures in
7 advance of a contingency.

8 Lastly, we will discuss the ongoing pilot program on
9 quality and safety of pharmaceuticals. The Department of
10 Defense Uniformed Services University of the Health Sciences
11 is leading a pilot program to assess pharmaceutical product
12 quality in the military health system pharmaceutical supply
13 chain. While this pilot program is in the early stages, we
14 utilize the military health system as a representative
15 example to conduct a thorough review of the pharmaceutical
16 supply chain to include a risk assessment analysis of our
17 domestic manufacturing capacity and analytical testing of
18 drug products from various suppliers.

19 I am deeply concerned by our lack of resiliency and
20 transparency in this area. I look forward to hearing the
21 results of this study over the coming years. And I want to
22 thank all of you for being here, and I simply do not
23 understand how we ever got ourselves dependent on China and
24 why we are not doing more to get it done.

25 Senator Warren: Thank you very much. Thank you,

1 Senator Scott.

2 As I said, our first panel is going to be about drug
3 shortages and R&D for the Department of Defense. And from
4 my left to my right we have Dr. Mark Dertzbaugh, Principal
5 Assistant for Research and Technology for the U.S. Army
6 Medical Research and Development Command; we have with us
7 Dr. Martinez-López -- it is good to see you -- the Honorable
8 Dr. Lester Martinez-López, Assistant Secretary of Defense
9 for Health Affairs at the Department of Defense -- welcome;
10 Dr. David Smith, Deputy Assistant Secretary of Defense for
11 Health Readiness, Policy and Oversight at the Department of
12 Defense; and Mr. Matthew R. Beebe, who is Legislative
13 Affairs Director at the Defense Logistics Agency.

14 And I understand, Dr. Lester Martinez-López, that you
15 are going to give a joint statement to get us started?

16 Dr. Martinez-López: And Mr. Beebe, as well.

17 Senator Warren: All right. And then Mr. Beebe will
18 speak. Thank you. You are recognized, Dr. Lester Martinez-
19 López.

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1 JOINT STATEMENT OF HON. LESTER MARTINEZ-LÓPEZ,
2 ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS,
3 DEPARTMENT OF DEFENSE; DAVID J. SMITH, M.D., DEPUTY
4 ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY
5 AND OVERSIGHT, DEPARTMENT OF DEFENSE; AND MARK DERTZBAUGH,
6 M.D., PRINCIPAL ASSISTANT FOR RESEARCH AND TECHNOLOGY,
7 UNITED STATES ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND

8 Dr. Martinez-López: Chairwoman Warren, Ranking Member
9 Scott, and distinguished members of the Senate Armed
10 Services Committee, I am pleased to represent the Office of
11 the Secretary of Defense to discuss the Department of
12 Defense's commitment to ensure access to safe and effective
13 pharmaceutical products we procure and use in the Military
14 Health System.

15 In this testimony we will inform the Committee about
16 the Department's initiative to maintain a secure
17 pharmaceutical supply chain, assuring our MHS beneficiaries
18 receive the highest quality pharmaceutical products
19 available.

20 Over the past few decades, production of most American
21 generic drugs, and particularly the ingredients needed to
22 make them, has moved overseas. With this movement, national
23 security supply chain concerns arise. Similar to civilian
24 health care groups and other parts of the U.S. government,
25 the Department's core areas of concern are unstable sourcing

1 of pharmaceutical and/or active pharmaceutical ingredients
2 and the availability of domestic manufacturing for
3 contingency scenarios.

4 Consistent with the National Biodefense Strategy,
5 Section 3.5, "Guidance on Agile Therapeutic Development and
6 production," and Executive Order 14017, "America's Supply
7 Chains," the Department is taking a range of actions to
8 address these vulnerabilities. Specifically reference to
9 the MHS policy efforts, the Department's pharmacy and
10 medical logistics teams established a Pharmacy Supply Chain
11 Risk Management Working Group. This group leverage existing
12 and new assessments of all aspects of the supply chain, with
13 focal areas on the critical pharmaceuticals for beneficiary
14 care that are on the Joint Deployment Formulary. We have
15 begun the development of policies and procedures based on
16 this effort to enable allocation of resources in the case of
17 supply chain disruption.

18 Another effort to generate insights, led by the
19 Uniformed Services University of the Health Sciences, we are
20 evaluating aspects of the MHS pharmaceutical supply chain,
21 to include domestic manufacturing capability, documentation
22 of the supply chain, and supply chain security and
23 resilience. Our objective, through our research initiative,
24 is to generate meaningful and actionable information on drug
25 and active pharmaceutical ingredient supply chain

1 resiliency. Using the MHS as a representative example, this
2 study will conduct a thorough environmental scan of the
3 pharmaceutical supply landscape, including a risk
4 assessment, analysis of the domestic manufacturing capacity,
5 and examination of the pharmaceutical supply chain,
6 analytical testing of drug products from various suppliers,
7 and study of proposed scoring systems and the associated
8 policy considerations. Through this study the MHS will gain
9 insights into which manufacturers, and associated supply
10 chains meet reliability essential to the Department's Joint
11 Deployment Formulary.

12 In addition to the USU-led work, the Defense Health
13 Agency Research and Development focuses on developing novel
14 solutions at Walter Reed Institute of Research. At WRAIR,
15 structural and computational biologists harness the latest
16 generation in electron microscopy, the next generation in
17 sequencing, monoclonal antibody generation, machine learning
18 technologies and novel adjuvants in design of the next-
19 generation vaccine candidates, which are then tested in
20 preclinical models.

21 Through a range of efforts evaluating the supply chain
22 vulnerability and resiliency we hope to drive more effective
23 care while preparing for any potential shortfalls in supply
24 chain.

25 In conclusion, I would like to sincerely thank you for

1 your continued support of military medicine and for inviting
2 me here to discuss the important issues surrounding the
3 health of our warfighters and our DoD beneficiaries. I look
4 forward to your questions.

5 [The prepared joint statement of Dr. Martinez-López,
6 Dr. Smith, and Dr. Dertzbaugh follows:]

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1 Senator Warren: Thank you, Mr. Secretary. Mr. Beebe?

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1 STATEMENT OF MATTHEW R. BEEBE, DIRECTOR OF ACQUISITION
2 (J7), DEFENSE LOGISTICS AGENCY

3 Mr. Beebe: Good afternoon, Madam Chair, Ranking Member
4 Scott, and distinguished members of the Senate Armed
5 Services Personnel Subcommittee. Thank you for the
6 opportunity to testify today. My name is Matt Beebe. I am
7 the Senior Procurement Executive for the Defense Logistics
8 Agency, or DLA, a Department of Defense combat support
9 agency. I am grateful to have the chance to speak to you
10 today about some of the work DLA is doing to improve
11 visibility and transparency within the DoD pharmaceutical
12 supply chain and ensure that our military servicemembers
13 have access to safe, high quality pharmaceuticals.

14 DLA's mission is to deliver readiness and lethality to
15 the warfighter always, and support our nation through
16 quality, proactive, global logistics. In support of that
17 mission, DLA manages the full spectrum of pharmaceuticals
18 for the military and their dependents all over the world, to
19 include supply to military hospitals.

20 Although our military customers set pharmaceutical
21 requirements based upon the needs of today's warfighters, it
22 is DLA who purchases those products and manages critical
23 end-to-end supply chain logistics to ensure that military
24 servicemembers get the pharmaceuticals they need, when they
25 need them. We accomplish this by leveraging commercial

1 capabilities and contracting with commercial distribution
2 companies who use their global networks of sources to
3 deliver FDA-approved medicines to servicemembers at military
4 treatment centers or wherever they are located throughout
5 the world.

6 In line with our logistics mission and to better serve
7 our customers and the warfighter, DLA is always seeking to
8 improve our ability to identify, manage, and mitigate
9 logistical and supply chain risks, including those impacting
10 pharmaceutical supply chains.

11 One area of focus in this issue is foreign dependency
12 of pharmaceuticals. A 2021 report by the DoD inspector
13 general identified that due to the dependency of the U.S.
14 commercial pharmaceutical market on ingredients from foreign
15 suppliers, a disruption of the supply chain of those
16 ingredients to domestic manufacturers had the potential to
17 cause drug shortages, which could ultimately compromise the
18 standards of care for military servicemembers.

19 Similarly, in November 2023, DoD submitted a report in
20 response to Section 860 of the National Defense
21 Authorization Act for fiscal year 2023, regarding risks in
22 DoD pharmaceutical supply chains. In that report, DoD
23 identified the defense supply chain for pharmaceuticals is
24 highly dependent upon foreign or unknown sources, in large
25 part due to the global nature of the pharmaceutical supply

1 chain for both finished products and active pharmaceutical
2 ingredients, or APIs.

3 DoD identified several pervasive information gaps that
4 hinder its ability to obtain visibility and transparency in
5 these supply chains, particularly the lack of readily
6 available and authoritative data on the sources of finished
7 generic drugs, their APIs, and other key ingredients.
8 Having this information would significantly improve our
9 ability to illuminate the complex pharmaceutical supply
10 chain and help DoD ensure that our military servicemembers
11 continue to have access to safe, high-quality
12 pharmaceuticals.

13 As the provider of critical pharmaceutical products to
14 our nation's warfighters, we are steadfastly committed to
15 working with the Department, other Federal agencies, and
16 Congress to strengthen our collective ability to identify,
17 mitigate, and prevent risks in the pharmaceutical supply
18 chain.

19 DoD and the Department sincerely appreciate your
20 interest in these issues. I look forward to addressing your
21 questions.

22 [The prepared statement of Mr. Beebe follows:]

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1 Senator Warren: Thank you, Mr. Beebe.

2 I am going to start with the first round of questions.
3 The Defense Health Agency provides care for about 9 million
4 people in the military health system, and that includes by
5 dispensing prescription drugs to servicemembers and to their
6 families.

7 Earlier this month, the American Society of Health
8 System Pharmacists announced that there were a record 323
9 active drug shortages during the first quarter of 2024.
10 That is an all-time high in the United States.

11 Dr. Martinez, you are in charge of ensuring the health
12 and safety of our servicemembers. When DHA cannot get a
13 critical drug because it is in shortage, can you just
14 explain to everyone what options you have to ensure that
15 servicemembers and their families are receiving the care
16 they need?

17 Dr. Martinez-López: Chairwoman, thank you for the
18 question. You know, the health of our beneficiaries is of
19 most importance to all of us, and when you face the issue of
20 not having the drug, the right drug for that patient then
21 your choices are to go and look at alternate drugs that may
22 not be exactly the same one for that condition or for that
23 patient. It may have a different side effect profile.

24 So let me give you an example. Amoxicillin may be a
25 drug. It is an antibiotic, made overseas, and used

1 everywhere for basic infections. But let's say I do not
2 have it. Now I have to take other antibiotic, and at the
3 same time I am trying to combat resistance of antibiotic. I
4 am using an antibiotic that is not indicated for that
5 condition. So there I lose twice, once because I am not
6 giving the right antibiotic to my patients but on top of
7 that I am losing ground on my fight against antibiotic
8 resistance.

9 In other events, like in an epinephrine injection, that
10 can be life or death. We do not have hours to decide what
11 the alternate is. So that may translate into a life, right
12 on the spot.

13 So this creates a conundrum for all health care
14 professionals, and it is not just us. It is across the
15 nation we are facing this.

16 Senator Warren: Okay. So worse health outcomes for
17 the patient and worse health outcomes for the system
18 overall, is what I am hearing you say.

19 According to the FDA, one of the leading factors
20 contributing to drug shortages is quality issues. For
21 example, an FDA inspection of a manufacturing plant in India
22 revealed a, quote, "cascade of failure" at the plant's
23 quality control unit. Investigators found problems with
24 systems to prevent microbial contamination, to keep
25 processing areas sterile, and to protect critical production

1 documents, including they found a trash bag full of records
2 that had been torn and doused in acid. The plant
3 temporarily closed, resulting in widespread shortages of
4 common chemotherapy drugs across the United States,
5 affecting both civilian and servicemembers.

6 As more of our drug supply chain moves overseas, these
7 kinds of quality concerns are going to become even more
8 common. So last summer, DoD launched a pilot with an
9 independent lab to test drug products for safety and
10 effectiveness. For example, it will test whether the drug
11 contains any contaminants, whether it contains the correct
12 dosage, and whether it has the expected potency.

13 The pilot study is going to look at 12 drugs on DoD
14 Operational Medicines List, which includes drugs that are
15 necessary for warfighting, and its Predeployment Medicines
16 List, which includes drugs that help servicemembers control
17 chronic conditions to meet standards for deployment.
18 Together the pilot will test medicines needed to stabilize
19 wounds, alleviate pain, and treat infections.

20 Dr. Smith, can you share why DoD thought it was
21 necessary to conduct this pilot study?

22 Dr. Smith: Thank you for the question, Senator Warren.
23 As we have noted, we are most concerned about ensuring the
24 access to safe and effective drugs, and as you noted we are
25 doing a number of studies, the 860 study that we have

1 referred to and then also the study for the Uniformed
2 Services University, that is evaluating, in particular, a
3 quality scoring tool by DeBastiani, that was published in
4 the Journal of the American Pharmacy Association just last
5 year as an additional factor for us to consider as we
6 purchase medications on the market. And you pointed out the
7 various FDA recalls and the issues that have been coming up.

8 Additionally, we have heard that within the generics,
9 where there are multiple manufacturers using the same API,
10 that there may be a variance in those generics. So we
11 thought with all of those factors it would be useful to
12 conduct this pilot study that you referred to, that
13 ultimately will look at 42 drugs from our Joint Deployment
14 Formulary, to see if we can differentiate between the
15 generics and make us actually a better buyer and actually
16 reward manufacturers that produce the product that is spot
17 on. Over.

18 Senator Warren: Good. So you are talking about a
19 study that you are doing because you hear a lot of problems
20 out there, and also this may help you figure out how to
21 respond to those going forward. Is that a fair summary?

22 Dr. Smith: I think that is fair.

23 Senator Warren: Good. Good. So when DoD is making
24 decisions about purchasing drugs, price is often the most
25 important consideration, but it should not be the only

1 consideration. Whether a drug is made by a reliable
2 manufacturer or whether its active ingredients are made, and
3 where they are made should also inform purchasing decisions.

4 The Defense Logistics Agency is responsible for
5 procuring pharmaceuticals on behalf of the Military Health
6 System, but DHA can put requirements on the purchases. Dr.
7 Martinez, if DoD identifies significant risks to the safety
8 of its drug supply chain will DHA add requirements on drug
9 quality to ensure that we are buying effective, safe, the
10 best drugs for our servicemembers?

11 Dr. Martinez-López: Senator, based on the information
12 the pilots give us, I think we will be in a position to, if
13 that is indicated, to make it so.

14 Senator Warren: Okay. So you can put that into your
15 requirements, and you are telling me that if you are
16 concerned about quality you will put it into your
17 requirements.

18 Dr. Martinez-López: Yes.

19 Senator Warren: For the drug. Good. That is what I
20 want to hear. You know, I am glad that DoD has taken steps
21 to evaluate drug quality, and the Department should be
22 prepared to use this information to improve quality and
23 accessibility of the prescription drugs that our
24 servicemembers need. Thank you.

25 Senator Scott?

1 Senator Scott: Thank you. Mr. Beebe, how many
2 different drugs do you buy in a year? How many different
3 ones?

4 Mr. Beebe: Well, our catalog probably is in the tens
5 of thousands of items. Of course, that is not all different
6 drugs. In some cases it is dosage differences, application
7 differences.

8 Senator Scott: Okay. Tens of thousands. All right.
9 And do you personally believe that we should not buy things
10 from Communist China?

11 Mr. Beebe: I agree basically, or in reality we follow
12 existing regulation on how and where to buy materials,
13 whether it be pharmaceuticals or other items.

14 Senator Scott: Sure. But do you believe that we
15 should not buy from Communist China?

16 Mr. Beebe: I agree, sir.

17 Senator Scott: Okay. So in the last 12 months, how
18 many drugs have we stopped buying from Communist China?

19 Mr. Beebe: When we buy pharmaceuticals we buy with a
20 preference towards domestic or safe, assured sources,
21 although in many cases we do not know where the sources are.
22 Normally we buy from domestic or our trading partners, but
23 we do not always have visibility of where the ingredients of
24 those pharmaceuticals come from, which is why it was so
25 important for us initiate the study and identify where we

1 believe the sources of the ingredients are.

2 Senator Scott: But today you could just say, "I am not
3 going to buy anything that has an ingredient that comes from
4 Communist China. You could say, "I am not going to buy
5 anything that has an ingredient from Communist China. I am
6 not going to buy anything that is packaged in Communist
7 China. I am not going to buy anything that is in any way in
8 the supply chain impacted in Communist China." You could do
9 that today, right?

10 Mr. Beebe: Actually, I do not believe the regulation
11 actually supports that, in that very often the final product
12 is manufactured domestically or from an ally, and if it is
13 substantially transformed in those countries it is in
14 accordance with trade agreements in the Buy American Act.

15 Senator Scott: So what is the limitation? Why can you
16 not make that decision today?

17 Mr. Beebe: Because often the final product is
18 manufactured either domestically or with an ally --

19 Senator Scott: But you could set that as a standard
20 and then it is a requirement -- you could set the standard
21 that whatever you buy can have nothing, anywhere in the
22 supply chain, comes from Communist China. You could decide
23 that today.

24 Mr. Beebe: If that standard exists, yes, but that is
25 not for DLA to decide. We have to follow existing

1 regulations and policy and --

2 Senator Scott: Who set regulations that said you could
3 not -- the Secretary of Defense testified the other day that
4 we should not buy anything from Communist China. So what
5 regulation would it be?

6 Mr. Beebe: That would establish that?

7 Senator Scott: Yeah. What regulation would stop you
8 from being able to do it today?

9 Mr. Beebe: I cannot say what that regulation would be,
10 but I certainly support being part of the discussion with
11 the Department of Defense.

12 Senator Scott: Why don't you just do it. Just do it
13 and see what happens. Why don't you just say tomorrow, you
14 just do it. Like I am a business guy. I negotiated
15 contracts with people. I ran the largest hospital company
16 in the country. I was the biggest buyer of pretty much
17 everything in health care on the provider side. And once I
18 signed a contract I said our hospitals could not buy
19 anything that day. They said, like that, and we are not
20 going to buy those gloves, that drug, that device. Why
21 don't you just do it?

22 Mr. Beebe: We do not buy end products from China
23 unless it is the only source available and we can justify
24 the waiver.

25 Senator Scott: So you believe that if there is a

1 product that there is a supplier in the United States today,
2 you do not buy anything made in China if there is supplier
3 of that product today?

4 Mr. Beebe: If the end product is available
5 domestically, that is where we will buy it, yes.

6 Senator Scott: Do all of you believe that? So if come
7 back and tell you that there are suppliers here that compete
8 with China, that cannot get contracts with you, you will be
9 shocked.

10 Mr. Beebe: If we are talking about the end product,
11 yes.

12 Senator Scott: What is the difference?

13 Mr. Beebe: Well, much of what we are talking about is
14 the active pharmaceutical ingredients that originate from
15 China that get molded into a final product. When we buy the
16 final product we are buying it from the United States or a
17 domestic trading partner, and we cannot, until recently, see
18 whether or not there were some ingredients from China or
19 other country of concern. It was not visible, and we are
20 working to make it visible.

21 Senator Scott: But why don't you just say, starting
22 today you will not contract, just put it out there, you are
23 not going to contract with anybody if anything -- not just
24 the active ingredients -- there is no part of the process
25 where Communist China is involved in it. There is none. Or

1 Russia, Iran, but primarily Communist China. Why don't you
2 just do it right now?

3 Mr. Beebe: If we made that absolute then we would be
4 creating a sufficient amount of non-availability for our
5 health professionals.

6 Senator Scott: But if you do not do it today, when are
7 you going to do it? I mean, if you do not start today, I
8 mean, when are you going to do it? If you do 10,000, why
9 don't you start off with 1,000 and see how bad it is? I
10 mean, I am just a business guy, and I did not buy from my
11 competition. This is not competition. These people are
12 trying to kill us. Oh, they are killing us. I mean,
13 Chinese precursors are killing 70,000 people with fentanyl a
14 year. So why don't you just do it?

15 What I am trying to understand is, I think all of you
16 agree Communist China wants to destroy our way of life. I
17 think we all would, right? Does anybody disagree?

18 [No response.]

19 Senator Scott: Nobody disagrees. So let's do it
20 today. What I do not understand is why don't we do it
21 today? I just do not get it. Can somebody explain to me why
22 we do not?

23 Dr. Smith: Sir, there are some of the APIs that only
24 originate from China, that are critical to medications that
25 we use on a daily basis. And so that would be one of the

1 impediments that needs to be resolved to be able to go that
2 direction, sir.

3 Senator Scott: So, Dr. Smith, how many is that?

4 Dr. Smith: I am aware on the Joint Deployment
5 Formulary, and this is specifically China, and as Mr. Beebe
6 pointed out we have an issue with provenance on a fair
7 percentage of our Joint Deployment, but I am aware, I
8 believe -- and I can take it for the record -- 27 drugs that
9 the APIs are specifically only sourced from China.

10 Senator Scott: And have we put out a bid for Americans
11 to say, will somebody do it, on those, those 27?

12 Dr. Smith: As part of our work on 860, it is part of
13 what we are going through to confirm and work solutions to
14 this issue. But we are well aware that there is a
15 substantial amount of the APIs, the active pharmaceutical
16 ingredients, that are coming from Mainland China. Over.

17 Senator Scott: So that is not 27 out of 10,000, right?

18 Dr. Smith: I should probably take it for the record,
19 sir, and we can give you the information. But I think it is
20 27 out of 920, or so.

21 Senator Scott: Okay. I am sorry.

22 Senator Warren: No, no. That is fine.

23 Senator Scott: I just want to understand why we do not
24 do it today. I mean, in business we would just say, guys,
25 we had a nice meeting. We found out that these people are

1 trying to destroy it. And we just say, okay, guys. We all
2 decide, as of today, we will not do business with them. We
3 do that in business all the time. I do not know why we just
4 do not do that. I do not know what the limitation is. If
5 there is a limitation, I want to all -- the Secretary of
6 Defense has told me he does not want to buy anything from
7 China.

8 Dr. Martinez-López: Sir, if I may, the main limitation
9 we have right now, like Dr. Smith said, is that some of
10 these drugs, the API is only made in China, and that is in
11 the global market. So if we decide not to buy Chinese, I
12 mean, I think the number is around 5 percent of it, that we
13 know of, of all the drugs in the formulary, that the API
14 comes from China. And we do not know about 20-something
15 percent of them where the API comes from. So that creates a
16 conundrum. So if we could source it some other place, that
17 would be great.

18 Senator Scott: Okay. So why would we not do this.
19 There are all these different options. Number one, what I
20 would do is just say I am not going to do it, and everybody
21 has to sign a contract that they will not do it, and let's
22 see what happens. I guess they will come back and tell us,
23 right. Or we could say you have got 90 days to tell us
24 where all your ingredients come from, and then we could make
25 a decision. But, I mean, in my business life I would not

1 say, "Let's do a study." I would say, "No, I am not going
2 to do it."

3 I am just trying to figure out, if there is an
4 impediment, just tell me what it is. Are you in the same
5 position I am?

6 Senator Warren: Yes, and I want to follow up on your
7 point. Okay, I just want to follow up on this about the
8 risks we run from having overseas manufacturing that is
9 either in China or some other nation that is not an allied
10 nation, because they all pose this risk and we need to worry
11 about it.

12 I mentioned in my opening remarks that Senator Rubio
13 and I got a provision in the fiscal year 2023 NDAA for DoD
14 to put together a report, and it came out last November,
15 about drug supply chain risks in military, and evaluated 211
16 drugs. And it found that half of those were either at high
17 or very high risk because the active pharmaceutical
18 ingredients, the APIs, for those drugs are sourced from
19 China or non-Trade Agreement Act countries, or are just
20 simply unknown, nobody knows where they are coming from.

21 So you identified, Mr. Beebe, that 27 APIs are sourced
22 exclusively from China, but I would just point out that is
23 only a little over 10 percent of the drugs. It is not half
24 the drug we are talking about here. We have got a lot more
25 drugs that if you right that it is only 27, then we have got

1 a lot of other drugs that are being sourced overseas, that
2 we think there is a substantial risk.

3 And so the question becomes whether or not we should
4 bring that manufacturing back to the United States. Is that
5 in our national defense?

6 So let me put that question to you, Mr. Beebe. Should
7 we be manufacturing these drugs domestically, and what is
8 the risk if we keep running these manufacturing facilities
9 overseas for China or non-Trade Agreement Act countries?

10 Mr. Beebe: So yes, ma'am. First of all, Dr. Smith is
11 the one that made reference to the 27 --

12 Senator Warren: Sorry. Sorry.

13 Mr. Beebe: -- but I will go ahead and address the
14 question first. So yes, we studied the FDA Essential
15 Medicine List, and that is what was the basis for the report
16 that identified a high amount of APIs sourced in China or
17 other non-TA countries. Since then we have doubled that
18 population, adding some of the highest volume
19 pharmaceuticals that are purchased by our medical treatment
20 facilities, as well as the overlap with the Joint Deployment
21 Formulary, to expand the amount that we have reviewed, and
22 the results are essentially the same, by percentage, as in
23 same percentage of those coming from countries of high risk
24 as well as the same percentage of unknown, which is, to me,
25 equally troubling that I do not even know how to

1 characterize the risk.

2 Do I support bringing more domestic capacity?

3 Absolutely. I mean, not only does domestic capacity mean
4 that we have better access, but it also means that the
5 government can better influence prioritization when there
6 needs to be decisions of priority.

7 Senator Warren: Okay.

8 Mr. Beebe: That is very important too. Yes, ma'am.

9 Senator Warren: So let's talk a little bit about what
10 is involved in increasing domestic manufacturing of these
11 pharmaceuticals. Last summer, DoD released its inaugural
12 DoD Biodefense Posture Review. This outlined the
13 Department's capabilities to counter biothreats and identify
14 domestic manufacturing as a priority reform initiative.
15 According to the Posture Review, we have reduced drug
16 manufacturing here in the United States so much that we
17 simply do not have the commercial capacity to manufacture
18 what our troops need. And because the Department's, quote,
19 "unique biodefense demands" are small and not commercial
20 competitive, reliable domestic manufacturing partners are
21 actually hard to find.

22 But that is not the end of the story. DoD has its own
23 manufacturing capabilities, capabilities with a proven track
24 record of success. In 2017, DoD's Advanced Development and
25 Manufacturing Biopharmaceutical Facility to help manufacture

1 medical countermeasures became fully operational. DoD has a
2 second biomanufacturing facility at the Walter Reed Army
3 Institute for Research, WRAIR. The Walter Reed facility has
4 developed many vaccines that DoD relies on today to protect
5 our troops from a number of diseases, including Zika, Ebola,
6 and adenoviruses.

7 So Dr. Dertzbaugh, you help oversee WRAIR, and WRAIR
8 has developed many essential products that both
9 servicemembers and civilian populations use today. Can you
10 explain why WRAIR was the best place to develop these
11 discoveries rather than just leaving it to private industry?

12 Mr. Dertzbaugh: Thank you, Chairwoman, for the
13 question. I appreciate the opportunity to talk about DHA
14 R&D's infectious disease research capabilities. Our two
15 laboratories, the Walter Reed Army Institute of Research and
16 then the U.S. Army Medical Research Institute of Infectious
17 Diseases, have the capabilities and the subject matter
18 experts to get after these infectious disease threats that
19 our servicemembers might encounter when they are deployed
20 overseas or fighting an adversary or even in training. So
21 those capabilities help us find countermeasures for
22 solutions to medical infectious disease threats that are not
23 commercially viable in the U.S. because there is no market
24 for this. There is no threat to the U.S. population, in
25 general.

1 Senator Warren: All right. That is very helpful.
2 Thank you. Because WRAIR's Pilot Biopharmaceutical Facility
3 has been crucial in addressing these potential threats and
4 keeping our servicemembers safe, especially when private
5 sector is not in a position to fulfill that role.

6 As DoD considers how to implement the recommendations
7 it has identified on domestic manufacturing, the Department
8 should also think about how to replicate the capabilities at
9 facilities like WRAIR to strengthen supply chain resilience
10 and to keep our members safe and bring that manufacturing
11 home. Thank you.

12 Senator Kaine?

13 Senator Kaine: Thank you, Madam Chair and Ranking
14 Member Scott, and I appreciate the witnesses being here. I
15 have two questions that I would like to ask. While reliance
16 on APIs from foreign countries that are adversaries presents
17 significant threats, the good news in this challenge is that
18 we are not alone. Not every other country is an adversary.
19 We have networks of alliances, unlike any of our
20 adversaries.

21 And so I wonder whether, and maybe I will start with
22 you Mr. Secretary, have we discussed this challenge with
23 nations with whom we have close economic, military,
24 diplomatic ties, and explored ways we can deal with those
25 challenges in a joint way?

1 Dr. Martinez-López: Thank you for the question,
2 Senator. The answer is yes. Actually, we talked with a
3 couple of allies, trying to figure out their ability to
4 produce all the drugs that could use. And to their
5 amazement and my amazement --

6 [Audio interruption.]

7 Dr. Martinez-López: -- we have to have a secure chain
8 of supply. I owe it to my servicemembers --

9 [Audio interruption.]

10 Senator Kaine: -- within the DoD, from antidepressants
11 to --

12 Dr. Smith: It is a wide range. Yes, sir.

13 Senator Kaine: What are we expecting to learn from
14 this, and I suspect that if we do learn something from this
15 data, the application is not just the military application.
16 This would be good information in the civilian space,
17 whether it is Medicare or civilian. It would be really good
18 to have that.

19 Dr. Smith: Yes sir, and I think as I had mentioned, we
20 are looking at this quality tool that was actually proffered
21 by a group of academic pharmacists last year to see whether
22 or not, indeed, we can differentiate by manufacturer. So we
23 are looking at all the in a particular drug and then doing
24 this additional -- I mean, clearly looking at all of the
25 good work that FDA and the regulatory piece does, but then

1 adding onto it testing, looking at potency, looking at the
2 dose, and also looking at contaminants that may be used as
3 fillers, et cetera, in the product.

4 And then if we find anything we have also contracted
5 with three other academic institutions to do validation of
6 that work. And if it pans out, we think it will help us
7 direct our buying towards those manufacturers that produce
8 what we would define as the highest quality products. But
9 it is a pilot, and that is why we have characterized it that
10 way, because we do not know, and I do not think this has
11 ever been tested, if you will.

12 Senator Kaine: I am talking about the timing of the
13 pilot and when do you expect it to start, you know, getting
14 good information back?

15 Dr. Smith: It is to run 2 years. We started the
16 actual work in November. They have just finished
17 contracting with the -- or I believe it is finished, but
18 they are in the process with these third-party or additional
19 partners. So we should start seeing beginning information.
20 As Senator Warren said and you have, we are doing the first
21 12 right now. But our intention is to do about 42 different
22 drugs. So I would anticipate that clearly by early next
23 year we will start flowing in, but the whole project is
24 scheduled over a 2-year period.

25 Senator Warren: Thank you. Senator Scott?

1 Senator Scott: Secretary, let's think about -- because
2 I think you are right, what you were talking about how we
3 can use this whole buying power idea. So let's think about
4 it. I have checked with the Chair to see if she would be
5 okay with this. But could you prepare a letter that we
6 would send out to basically all of the health care community
7 -- you know, we could do it through like the hospital
8 association, pharmaceutical, everybody -- and say this is
9 the problem, you guys have the buying power, we believe we
10 ought to create a domestic market. And so everybody starts
11 doing their part.

12 So, the way I would think about doing it is, number
13 one, if the Chair is okay with this, we would do it with
14 you, and send a letter out to the entire health care
15 community. I think they would probably read it if it came
16 from you and from us, and talk about what you are doing, the
17 concern that you have addressed today. And then maybe wait
18 30 or 60 days, and then invite all the associations together
19 on a conference call to answer their questions, and get
20 ideas from them about what we could do to help build a
21 domestic market.

22 Dr. Martinez-López: Senator, that is a very intriguing
23 proposition. I have not thought about it. But really I
24 would like to be part of it, but it has to be really the
25 whole government. So ask for help from HHS and other

1 agencies. HHS has the lead for the country in this
2 particular issue. And obviously I would have to clear it
3 with the Secretary to make sure that it is appropriate. And
4 if it is, we will pursue it.

5 Senator Scott: So let's do this. If it is okay with
6 the Chair, let's start with us. If we can get other people
7 to sign on, HHS, all these people, that is great. If they
8 do not, let's go forward if we can. If not, we can do it,
9 if the Chair is okay with it. And then after that let's do
10 a call and tell them why this does not work.

11 Dr. Martinez-López: Senator, you may well know, we
12 need to ask, but if I get that from my Secretary then I will
13 be more than glad to lead the effort.

14 Senator Scott: Let me know, because he said in
15 testimony that he did not want to buy anything from
16 Communist China.

17 And then, Mr. Beebe, I think we all would like to have
18 something happen. So could you come back, maybe -- I do not
19 know what is appropriate, whatever you think is appropriate
20 -- and maybe meet with the Chair and me and our staff and
21 just say, okay, what is the limitation and what can we do
22 today. And if you tell us there is a limitation, then I
23 think at least the three of us that are here, I think we are
24 all on the same page -- and it is just crazy that we are
25 doing this to ourselves, and being dependent on China -- we

1 are all on Armed Services, and we will work hard to get it
2 affixed to the NDAA. I do not know if that makes sense to
3 you. Is that doable? Thirty or 60 days, is that realistic?

4 Mr. Beebe: Yes, sir. I mean, absolutely, we want to
5 be part of the solution. The illumination we are doing to
6 try to identify the sources is the beginning of having some
7 information to use towards that dialogue, to figure out how
8 we can move the market or adjust the market. And I will be
9 glad to respond.

10 Senator Scott: Let's try to do it in 30 days. The
11 NDAA is coming up this year pretty quick now, because it is
12 May 1 tomorrow, right. But the faster you can do it, the
13 three of us will work with you.

14 Mr. Beebe: I would offer that because that is very
15 much a policy discussion that we would want to include the
16 other stakeholders from the Department.

17 Senator Scott: Sure. But, I mean, we have Paul on our
18 team, and I know you have great people on your team. We
19 will work with you. But the faster we do it, there is a
20 greater chance the three of us can get it in the NDAA this
21 year.

22 Senator Warren: Let's make sure we have got Mr.
23 Dertzbaugh on this, as well, since I see WRAIR is the model
24 for when the market has a complete breakdown and cannot
25 produce what it is that our military needs.

1 Mr. Dertzbaugh: Ma'am, if I may speak, that is true to
2 a point, I would say. We certainly have the ability in our
3 production facility to make small quantities of vaccines.
4 It does not have the ability to make any drug products,
5 though. And we are still reliant on commercial
6 manufacturers to produce large quantities of those materials
7 if we are going to use them.

8 Senator Warren: I understand that you are small, but
9 successful. But I also understand, and I hope you are
10 hearing here, all of you are hearing, how committed we are
11 to redomesticating our pharmaceutical supply chain and
12 production. And I think you are going to be part of that,
13 as well. Good. We good? Senator Kaine, you good?

14 Senator Kaine: I am good.

15 Senator Warren: All right. Thank you all. I
16 appreciate you being here today. And I ask for Panel 2 to
17 come in. Thank you.

18 [Pause.]

19 Senator Warren: Thank you. Thank you for being with
20 us. The second panel will feature testimony that clarifies
21 DHA's existing authorities to insulate servicemembers from
22 drug shortages and offers additional solutions.

23 We have with us today, again from my left, Dr. Melissa
24 Barber, a postdoctoral fellow at the Yale Collaboration for
25 Regulatory Rigor, Integrity, and Transparency; Dr. Bryce

1 H.P. Mendez, a Specialist in Defense Health Care Policy at
2 the Congressional Research Service; and Mr. Victor A.
3 Suarez, a retired U.S. Army colonel, and Founder and
4 Principal Growth Partner of Blu Zone Bioscience & Supply
5 Chain Solutions, LLC.

6 So I will start the first round of questioning here.

7 Most of the time, DoD will continue to purchase drugs
8 from the commercial drug market.

9 Oh, I am so sorry. I am so eager to get to them. I
10 apologize. If we could we still start with our testimony.
11 Dr. Barber, would you like to start us, please?

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1 STATEMENT OF MELISSA BARBER, Ph.D., POSTDOCTORAL
2 FELLOW

3 Dr. Barber: Chair Warren, Ranking Member Scott, and
4 members of the Subcommittee, thank you for the invitation to
5 testify today. I am a postdoctoral fellow at Yale
6 University, researching pharmaceutical markets.

7 Both here and in my written testimony I will endeavor
8 to report, as precisely and honestly as I can, evidence from
9 the academic and policy literature on drug market failures
10 and other remedies. My remarks today reflect my own views,
11 not the view of my employer or any other organization.

12 No one here today disputes that the military faces
13 challenges in ensuring a reliable supply of safe, high-
14 quality pharmaceuticals. No one here today disputes the
15 unacceptable risks this creates for the health and well-
16 being of servicemembers and their families, as well as
17 operational readiness. So the task before us then is to
18 unravel the root causes of challenges in the supply chain
19 and to develop solutions.

20 First, military procurement of medicines is exposed to
21 many of the problems seen in broader commercial markets for
22 medicines, including increasing costs and supply and
23 stability. Supply chains for many drugs are vulnerable to
24 interruption. We do not even know the scale of the problem.
25 A recent report by DoD noted that they could not determine

1 the API source of 22 percent of drugs. But within the
2 academic literature we find that approximately one-third of
3 generic active pharmaceutical ingredients produced for use
4 in U.S. markets were manufactured by a single facility, and
5 an additional third were manufactured by only two or three
6 facilities.

7 This Committee may not have jurisdiction over
8 industrial policy, but it still must reckon with the
9 downstream results of decades of policy decisions that have
10 resulted in the concentration and offshoring of most
11 pharmaceutical production.

12 Second, economists widely agree that markets for
13 medicines do not always behave like typical markets and are
14 far from being few or competitive. We should leave our
15 idealized, orderly supply and demand curves in the
16 cloakroom. They will not be of much use to us this
17 afternoon as theoretical lenses. We have to instead
18 understand these markets on their own terms and through
19 rigorous analysis of empirical data.

20 Markets for medicines for military use are even more
21 unusual. One factor is many are national monopolies and
22 monopsonies because they involve hyper-specialized goods,
23 often produced in quantities too small to be manufactured
24 cost-effectively by more than one company. A review of DoD
25 contracts shows many such hyper-specialized products, all

1 the way from anthrax vaccines, battlefield-suitable
2 analgesic auto-injector kits and nerve agent antidotes, to
3 the specialized medicines used by California sea lions that
4 the U.S. Navy trains for defense purposes. When there is
5 only one buyer and seller, the DoD is not bidding in a
6 competitive market. The DoD is the market, and that demands
7 that we think about market problems and market solutions in
8 a nuanced, context-specific way.

9 Third, for some drugs there is an irreconcilable
10 mismatch between commercial incentives and defense needs,
11 which cannot be solved with purely market-based solutions.
12 Pharmaceutical companies are incentivized to manufacture a
13 drug if it gives them a good return on investment. A supply
14 line that manufactures an expensive cancer drug that serves
15 a wide market is just more profitable than manufacturing
16 drugs with small markets, like anthrax vaccines or drugs
17 with low margins, like off-patent antibiotics.

18 In contrast, the military is conscious of costs but is
19 ultimately incentivized to purchase drugs that meet
20 operational needs and protect the health of servicemembers.
21 Sometimes, but not always, these incentives overlap, and
22 when they do not, one often-tried solution to bridge that
23 gap is to pay pharmaceutical companies enough that it
24 becomes worth their while to manufacture the drugs the
25 military needs. For products used mostly or only by the

1 military, we have seen time and time again that the expected
2 demand has not been sufficient to generate a healthy number
3 of bidders.

4 We therefore have to be realistic about when the DoD
5 will be able to buy itself out of market failures. The DoD
6 just does not have the spending power to fundamentally
7 change the incentives that govern the commercial market to
8 serve defense needs. DoD spending, as many have spoken
9 today, accounts for less than 2 percent of overall spend in
10 the United States.

11 These limitations of using commercial markets to ensure
12 a resilient supply chain for military needs bring me to my
13 final point. When it comes to medicines for military use,
14 we live, and have always lived, in a mixed economy. By this
15 I mean that the public and private sectors have both played
16 an important role in developing, manufacturing, and
17 supplying medicines in the United States for over 160 years.
18 The private sector has efficiently supplied DoD with many
19 needed medicines.

20 However, for many other medicines where the military is
21 the sole market, or the commercial market has struggled to
22 meet military needs, the military has brought manufacturing
23 in house. The history of the military producing medicine
24 stretches back to at least the Civil War, when
25 pharmaceutical manufacturing facilities were established in

1 Philadelphia and Astoria to stabilize supply chains for the
2 Union army, with many other examples outlined in my written
3 testimony.

4 The public sector, more generally, has solved puzzles
5 that the private sector was not incentivized to explore,
6 like how to manufacture penicillin, and the public sector in
7 the United States continues to successfully manage products
8 as complex as vaccines and monoclonal antibodies today.

9 We cannot afford to hold onto the hope that markets
10 will always sort themselves out. At present, government
11 creation of manufacturing capacity is usually done
12 reactively, with initiatives created in response to
13 particular crises. As one example, it took over 10 years
14 and \$100 million for DoD to bring adenovirus vaccine
15 manufacturing back online after Wyeth, the sole supplier,
16 held DoD to ransom, to renovate the facility at excessive
17 cost.

18 I bring up this history to dispel any misconceptions
19 about military drug production as a new idea, rather than as
20 an idea older than the Department of Defense itself. In my
21 written testimony I detail independent review after
22 independent review, recommending that the military build on
23 past successes and existing capacity and bring the
24 manufacturing of priority products back in house. I also
25 detail decades of bipartisan support for this from the

1 Congressional Record.

2 Today I echo their conclusions in recommending that
3 Congress introduce legislation establishing clear options
4 for creating a government-owned facility to manufacture
5 priority health products to meet unmet DoD needs. Thank
6 you.

7 [The prepared statement of Dr. Barber follows:]

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Senator Warren: Thank you, Dr. Barber. Mr. Mendez.

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1 STATEMENT OF BRYCE H.P. MENDEZ, SPECIALIST IN DEFENSE
2 HEALTH CARE POLICY, CONGRESSIONAL RESEARCH SERVICE

3 Mr. Mendez: Good afternoon, Chairwoman Warren, Ranking
4 Member Scott, and members of the Subcommittee. Thank you
5 for inviting the Congressional Research Service to testify
6 today.

7 This afternoon I will summarize my written statement by
8 starting with a brief overview of the medical research and
9 development capabilities of the Department of Defense, or
10 DoD, followed by a summary of why and how the Department
11 aims to use those capabilities to develop drugs. I will
12 conclude by identifying considerations that Congress may
13 face with regard to DoD medical research, development, and
14 manufacturing of these products.

15 The U.S. military has a long history of contributing to
16 the discovery of novel drugs and other medical
17 countermeasures. Early and well-known contributions took
18 place during and shortly after the Spanish American War when
19 Army medical research efforts supported the discoveries of
20 typhoid, yellow fever, and malaria vaccines. The lessons
21 learned from the Spanish American War, and other conflicts
22 throughout our nation's history, have laid the groundwork
23 for Congress and DoD to invest in, build, and sustain
24 military medical research and development capabilities.
25 Today, DoD uses these capabilities to protect servicemembers

1 from health threats, respond to medical capability
2 requirements of the joint force, meet the needs of the
3 National Defense Strategy, and to also respond to
4 congressionally directed research topics.

5 DoD medical research and development enterprise
6 includes a number of entities like the Defense Health
7 Agency, the military departments, Defense Advanced Research
8 Projects Agency, and the Chemical and Biological Defense
9 Program, among others. Congress appropriates research
10 funding to these entities, who are then responsible for
11 resourcing, performing, or sponsoring medical research
12 projects.

13 Two of these entities, in particular, provide DoD with
14 capabilities to develop drugs using different approaches.
15 One capability is the Pilot Bioproduction Facility at the
16 Walter Reed Army Institute of Research in Maryland. This
17 government-owned facility provides a test ground for Federal
18 agencies, academia, and private companies to pursue early
19 development and small-scale production of drugs so that they
20 can be transitioned into advanced clinical trials.

21 Another capability is the Advanced Development and
22 Manufacturing Biopharmaceutical Facility in Florida,
23 administered by the Chemical and Biological Defense Program.
24 The contractor-owned, contractor-operated facility, which
25 became operational in 2017, provides DoD with priority

1 access and surge capacity to produce medical
2 countermeasures.

3 When DoD discovers a potential drug candidate, the
4 Department is generally subject to Food and Drug
5 Administration, or FDA, requirements and procedures for
6 review, approval, and clearance. Since at least 1997,
7 Congress has provided DoD with an ability to request a
8 presidential waiver of certain FDA requirements, including
9 those for administering investigational new drugs, or off-
10 label uses of a drug, and informed consent for certain
11 products authorized for emergency use.

12 In 2017, Congress provided the Secretary of Defense
13 with the ability to make requests to the FDA Commissioner
14 for expedited review, approval, and clearance of certain
15 medical products when there is an existing or potential
16 military emergency. These authorities provide frameworks
17 for DoD and FDA to share information and to collaborate and
18 coordinate on the development of safe and effective medical
19 products that serve the military's needs.

20 Turning now to the role of Congress, I wanted to
21 highlight two issues that this Subcommittee may face.
22 First, Congress could consider defining or clarifying the
23 role that DoD should have in conducting in-house drug
24 manufacturing. A question that Congress could consider is
25 whether or not DoD should be in the business of

1 manufacturing drugs or other medical products, and if so,
2 for what purpose and to what extent?

3 Second, Congress could consider assessing DoD's medical
4 research development and manufacturing approach to better
5 understand its effect on industry participation or
6 engagement with the Department. Congress has given DoD
7 certain authorities and tools that it may use to generate
8 interest and incentivize industry to work with the military.
9 These authorities and tools include unique contracting
10 mechanisms, technology transfer opportunities, and a process
11 for expedited FDA reviews and approvals. Congress could
12 evaluate whether DoD has used these authorities and tools as
13 Congress intended and explore how they might attract,
14 influence, or deter companies from doing business with the
15 military.

16 This concludes my remarks. Thank you for the
17 opportunity to testify, and I look forward to your
18 questions.

19 [The prepared statement of Mr. Mendez follows:]
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1 Senator Warren: Thank you, Mr. Mendez. Colonel
2 Suarez.

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1 STATEMENT OF COLONEL VICTOR A. SUAREZ, USA (RET.),
2 FOUNDER AND PRINCIPAL GROWTH PARTNER, BLU ZONE BIOSCIENCE &
3 SUPPLY CHAIN SOLUTIONS, LLC

4 Colonel Suarez: Good afternoon, Chairwoman Warren,
5 Ranking Member Scott, and distinguished members of this
6 Committee. Thank you for the opportunity to speak with you
7 today.

8 My name is Vic Suarez, and I have recently retired from
9 the U.S. Army after 27 1/2 years of active service, as a
10 medical service and acquisition corps officer, specializing
11 in the advanced development of biologics, managing the
12 medical supply chain, and meeting America's finest sons and
13 daughters as a commander four times, twice in the combat
14 zone.

15 During the past 10 years I have been heavily involved
16 in advanced development of biodefense medical
17 countermeasures, served as the Chief of Staff at the Walter
18 Reed Army Institute of Research, and was selected by General
19 Gus Perna to serve at Operation Warp Speed, from 2020 to
20 2021 as the Lead Vaccine Program Manager. I am speaking
21 today primarily in my role as a Founder of Blu Zone
22 Bioscience, a life science consulting firm.

23 When I left active duty 6 months ago, my principal goal
24 was to affiliate with organizations that were mission-
25 aligned with my responsibilities in the DoD, including

1 enhancing national security and protecting human health, and
2 to that end supporting domestic companies that could support
3 those two missions. To this end, I partnered with two
4 organizations, the Council on Strategic Risks and the
5 Securing America's Medicines and Supply coalition. Both
6 organizations are focused on ensuring access to essential
7 medicines for patients and the warfighter.

8 On November 27, 2023, the Department of Defense, in
9 response to the fiscal year 2023 National Defense
10 Authorization Act, Section 860, provided the Senate and
11 House Armed Services Committee an interim risk report on the
12 Department's reliance on overseas-derived pharmaceuticals.
13 A significant finding was that 54 percent of the national
14 drug codes sourced from the DoD had active pharmaceutical
15 ingredients, or APIs, and excipients non-API, that came from
16 non-Trade Agreement Act compliant countries, including
17 China.

18 This recent finding presents a clear and present danger
19 to national security. It should compel us to explore better
20 legislative and trade policies that strengthen our Federal
21 acquisitions, economic, and health security to reduce our
22 reliance on overseas essential medicines, their key starting
23 materials, and API. We must manufacture more of these
24 materials domestically to ensure high-quality manufacturing
25 processes and products, including a reliable and resilient

1 material medical supply chain supporting this essential
2 industry.

3 A major contributing factor to this national security
4 and health security risk is a little-known but controversial
5 court case titled Acetris Health, LLC v. United States. In
6 this case, the United States Court of Appeals for the
7 Federal Circuit overruled a long-standing precedent
8 regarding the origin of a drug by ruling that a drug could
9 be considered to be manufactured or substantially
10 transformed in the U.S. and sold to the Federal Government,
11 even if its API and all of its components, to include
12 excipients, were manufactured in TAA-banned countries.

13 Today, a Chinese firm could make all the API and
14 precursor materials for a medicine, ship it to a U.S.
15 subsidiary that does packaging and final labeling, and still
16 be able to label it as American made. This would be
17 considered an American-made drug and principally illustrates
18 this loophole.

19 In my testimony today I wish to highlight a
20 dysfunctional market where generic drug companies compete in
21 a race to the bottom in generic drug pricing and
22 manufacturing, a principal driver of drug shortages, which
23 just 2 weeks ago, as you mentioned earlier, Senator, was
24 reported by the American Society of Health System
25 Pharmacists, that our nation is at an all-time high, since

1 2001, of 323 known drug shortages.

2 Overwhelming downward pressure in generic drug costs
3 with no consideration for supply reliability or quality
4 leads domestic manufacturers to operate at approximately 50
5 percent utilization capacity. Many of these domestic
6 companies are closing plants and essential medicine
7 production lines, or being acquired by foreign entities,
8 which will only downgrade our nation's ability to
9 independently provide health care for its citizens during a
10 global pandemic or during a national security event.

11 Finally, I want to applaud the Department of Defense
12 efforts to assess these strategic risks through both the
13 assessment of the origin supply chain at the Defense
14 Logistics Agency as well as the Uniformed Services
15 University Pharmaceutical Assessment of Quality Pilot Study,
16 or PhaQS, as both these efforts will provide more
17 transparency and potentially enable millions of our service
18 men and women, their families, and other TRICARE retiree,
19 like me, confidence that when they go to a military
20 treatment facility in the U.S. or serve in combat that they
21 will always have access to the highest quality medicines, at
22 the most affordable prices, something that is possible if we
23 are willing to disrupt the status quo.

24 Thank you for your attention as I raise these
25 significant considerations concerning our nation's

1 overreliance on non-Trade Agreement Act nations for our
2 pharmaceuticals, and I encourage Congress, and this
3 Committee, in particular, to closely monitor and support the
4 DoD's efforts to care for our warfighters, their families,
5 and retired military.

6 I look forward to your questions.

7 [The prepared statement of Colonel Suarez follows:]

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1 Senator Warren: Thank you, Colonel Suarez. I
2 appreciate it.

3 I am going to start the questions here. Most of the
4 time DoD will continue to purchase drugs from the commercial
5 drug market, but there are some instances when it makes
6 sense for DoD to produce the medication itself, for example,
7 when DoD is the only customer. An example is the adenovirus
8 vaccine. While adenovirus typically causes mild cold or
9 flu-like symptoms, it is a major cause of serious
10 respiratory illness among servicemembers, particularly
11 during basic training. And that is why WRAIR developed an
12 adenovirus vaccine which it then licensed to private
13 industry.

14 But because there is not a broad market for the
15 adenovirus vaccine, it has sometimes been difficult to find
16 a manufacturer that was willing to produce it. In fact, for
17 over a decade, DoD was unable to vaccinate new recruits for
18 adenovirus because the manufacturer decided to stop
19 producing the vaccine, and there was no other manufacturer
20 who was interested in doing this.

21 Mr. Mendez, you have studied the defense health care
22 system closely. First, let's start with, how did this
23 disruption affect the health of servicemembers?

24 Mr. Mendez: Thank you for the question, Senator. And
25 that is correct. DoD exhausted their last supply of the

1 adenovirus vaccine in about 1998, 1999. At that time, DoD
2 estimated that the absence of that supply of vaccine would
3 lead to about over 10,000 preventable infections from the
4 adenovirus, over 4,200 medical visits of recruits in the
5 recruit training pipeline, who are at risk for adenovirus,
6 and over 850 hospitalizations, within a year, to an extent
7 DoD did observe that in the absence of the vaccine.

8 Senator Warren: Okay. So in other words people got
9 sick, they had to go to the doctor. There were deaths
10 associated with this adenovirus. And all of that
11 potentially affects warfighter readiness. You have got all
12 these young people who are together, and the disease is
13 moving among them, right? The virus is moving among them.

14 So Dr. Barber, you are an expert on pharmaceutical
15 manufacturing. What did it take to finally get a new
16 manufacturer to produce the adenovirus vaccine for DoD?

17 Dr. Barber: After stocks were depleted in 1999, DoD
18 does what it usually does. It put out a tender, and the
19 previous manufacturer that had pulled out of the market,
20 Wyeth, they agreed to do a tech transfer, but only if DoD
21 would reimburse them for it, which is quite the demand
22 given, as we heard today, DoD developed that vaccine and had
23 done tech transfer to them free of charge in the first
24 place.

25 Only one manufacturer even considered bidding at the

1 time, Greer, but they withdraw because they asked DoD for
2 \$10 million up front, and DoD could not agree to it at the
3 time.

4 All in all, it is estimated that it took about \$100
5 million and 10 years for new vaccines to become available
6 again.

7 Senator Warren: You know, this is just stunning. DoD,
8 as you say, does the research, develops the vaccine, gives
9 it away to try to be able to get a manufacturer going, and
10 they end up paying a private manufacturer, I think you said
11 \$100 million. Is that about right?

12 Dr. Barber: In the end, yes.

13 Senator Warren: In the end, in order to build a
14 facility to manufacturer this vaccine that we need, on top
15 of the money they paid to purchase the vaccine from the
16 manufacturer, all because DoD is at the mercy of private
17 actors who just are not interested in marketing these
18 products for a relatively small market.

19 Mr. Mendez, is the adenovirus vaccine the only example
20 of a product that the private market has been unwilling to
21 manufacture for DoD/

22 Mr. Mendez: No. The adenovirus is not a unique case.
23 DoD has many challenges in finding a lot of medical
24 countermeasures, over many decades. Current challenges that
25 they experience and are working through include products to

1 address anthrax, botulism, cholera, hemorrhagic fevers,
2 tularemia, and other health threats.

3 Senator Warren: All right. You know, this is a real
4 problem, when the market just does not meet what it is that
5 DoD needs, and this is going to continue. We are going to
6 continue to have medications that DoD requires in order to
7 keep servicemembers healthy, and that simply are not
8 profitable for private industry to come in and produce.

9 Dr. Barber, what would be the advantages if DoD decided
10 to manufacture these drugs itself?

11 Dr. Barber: A public manufacturer is likely, depending
12 on the drug, to be enormously cost saving. To bring back
13 the adenovirus example, the current contract with Teva is
14 worth about \$38 million per year. That is actually a lot of
15 money to pay for a single vaccine. As a point of
16 comparison, it is about 80 percent annually of how much
17 California has budgeted to build an entire insulin factory.

18 A report by the Army estimated adenovirus factory
19 startup cost at \$100 million, with annual costs to \$10
20 million per year. So that works out to DoD breaking even
21 from building and running a manufacturing facility in just 3
22 years.

23 Besides costs, by manufacturing their own drugs, DoD
24 could ensure reliable supply and support wider strategic
25 aims and restoring domestic production capacity.

1 Senator Warren: Okay. So you pencil this out and
2 discover at least for some of these drugs it would be
3 cheaper for DoD to manufacture it themselves, and it would
4 have the added benefit of you know what your supply chain
5 is, there would not be any secrets in the supply chain, and
6 we would have a reliable source for these drugs.

7 This is why I am introducing a new bill, the Keep DoD's
8 Drug Supply Secure Act, to direct DoD to manufacture the
9 drugs, devices, vaccines, and other medical products when
10 there is a risk of shortage or quality concerns. This bill
11 gives us an opportunity to resolve drug shortages, to secure
12 the pharmaceutical supply chain, and to ensure safe and
13 effective drugs for our servicemembers. Thank you.

14 Senator Scott.

15 Senator Scott: Thank you, Chair. Colonel Suarez, So
16 you heard the testimony before, and Mr. Beebe said there are
17 about 10,000 drugs that they buy. Does that sound about
18 right?

19 Colonel Suarez: When we are talking about national
20 drug codes, we are talking in the thousands. So between
21 5,000 to 10,000 that they can source from within the
22 industry for pharmaceuticals.

23 Senator Scott: All right. So today, is there just
24 even one of those that they could just say, "Today I'm not
25 going to buy anything else from China?" Do you know of any

1 one of them that they could do that?

2 Colonel Suarez: No, but I think the fundamental issue
3 that they could probably do that is with help from the
4 Congress to address the loophole I mentioned in my opening
5 statement. The Department tried to do this -- and I am
6 talking the VA -- back in 2019, and they were challenged in
7 court when they wanted to execute an executive order to buy
8 American products. And they were challenged by this
9 company, Acetris Health, to say, well, we make this product
10 overseas, and then we do the final packaging and labeling in
11 the United States, and we are going to call it United
12 States. Well, that is not how precedent was defined for a
13 Made in America drug. That was always defined by where the
14 API was made.

15 Senator Scott: So you think we have to have a law that
16 says that Made in America means something different than
17 what that court case said?

18 Colonel Suarez: Yes. I think this is an
19 opportunity --

20 Senator Scott: Can you get that to us?

21 Colonel Suarez: Yes.

22 Senator Scott: And I will work on that. Okay. So
23 let's say we get that fixed. Is there anything else that
24 would prevent us from somebody in Mr. Beebe's position from
25 just saying, "Today we are not buying any more"? What else

1 would there be? Any other limitation?

2 Colonel Suarez: I think some of the challenges that
3 could be there is especially in those areas where we are
4 solely reliant on a supply chain that is only made in China,
5 for example. So right now if you look at the API Innovation
6 Center, they have really done some studies where they have
7 looked at the supply chain. They call out 60 vital
8 medicines in the United States. They estimate of the 60
9 vital medicines in the United States, about 20 percent of
10 them are solely sourced with APIs from China, and then for
11 key starting materials, it is about 45 percent of those
12 vital medicines are solely sourced -- that means there is no
13 other supplier.

14 Senator Scott: Just go back, on solving the problem.
15 Is the only limitation is if we get a law passed that says
16 that Made in America means X, that it is all produced here,
17 we do not use any of their ingredients, blah-blah-blah, and
18 no packaging, nothing, so is that going to give the
19 Department of Defense the ability to fix it today?

20 Colonel Suarez: I think when that loophole is closed I
21 think it gives a clear pathway to do what you are
22 suggesting.

23 Senator Scott: Okay. And that is the only limitation.

24 Colonel Suarez: I do not think that is the only
25 limitation.

1 Senator Scott: What else would it be?

2 Colonel Suarez: I think an understanding that having
3 quality differentiation in the marketplace other than cost
4 is another big hurdle for us to try to grapple with. And
5 this is dealing with the status quo --

6 Senator Scott: Oh, are you saying that they decide
7 based on price and nothing else?

8 Colonel Suarez: What I am suggesting is that the
9 marketplace for generic small-molecule pharmaceuticals is
10 primarily based on a cost basis, and no real measure of
11 quality in that decision matrix.

12 Senator Scott: So I am a business guy. In business, I
13 would not buy just based on price.

14 Colonel Suarez: Correct.

15 Senator Scott: Do you think we do that?

16 Colonel Suarez: Unfortunately, that is where the
17 market is going for that commodity.

18 Senator Scott: Why?

19 Colonel Suarez: Because what has happened over the
20 last couple of decades -- and this really happened around
21 late 2021, when we voted for China to be a Most Favored
22 Nation, and they all of a sudden grew their economy and we
23 started to transition our manufacturing overseas -- what
24 they found was they used their most competitive advantages,
25 and that is access to cheap labor and their inability to

1 really focus on environmental concerns in manufacturing.

2 So they could lower the price of goods very low, to the
3 point where they could target specific industries, like the
4 pharmaceutical industry, and even specific drugs, and
5 actually push some of our companies either out of business
6 or from stopping making critical medicines.

7 Senator Scott: So is there anything else we need to do
8 to stop it?

9 Colonel Suarez: I think part of it also is you could
10 leverage Defense Production Act to incentivize and pass
11 legislation for funding to actually bolster our domestic
12 supply chains and manufacturing in the United States. You
13 created incentives for the marketplace to say, hey, there is
14 an initial incentive, just like the CHIPS and Science Act,
15 to manufacture in the United States.

16 Senator Scott: So why do they not do it now. We have
17 got the Defense Production Act right now. Why don't they
18 just do it?

19 What I do not get is everybody -- I think we have all
20 come to the conclusion China is bad. They want to destroy
21 our way of life. Why are we buying their crap?

22 Colonel Suarez: Part of it is because in the past 20-
23 plus years they have done a very masterful job of
24 integrating into our biotech and biopharma and many
25 pharmaceutical manufacturing industries. They started with

1 early innovative companies, when they are small biotechs and
2 they are desperate because they are cash strapped. So they
3 basically hire them as contract research organizations. And
4 they develop those drugs and products throughout the life of
5 that drug application. So as that company matures and it
6 gets licensure, their entire supply chain might be dependent
7 on materials from China.

8 Senator Scott: So do we need to prevent China from
9 being able to invest in our pharmaceutical industry?

10 Colonel Suarez: What I would suggest to the Congress
11 is that they place limits on those known companies that have
12 either stolen intellectual property or have a bad intent to
13 take American technology --

14 Senator Scott: Do we need legislation, or can they do
15 that on their own right now?

16 Colonel Suarez: Well, so companies can make those
17 decisions --

18 Senator Scott: No. Can the Department of Defense
19 prevent a Chinese company from investing?

20 Colonel Suarez: I do not know if the Department could
21 do that directly without getting challenged in court.

22 Senator Scott: I do not get this. I mean, we do not
23 buy stealth bombers from China, so why do we buy drugs from
24 China?

25 Colonel Suarez: So what I would offer is that when you

1 look at things like the Berry Amendment, those were
2 originally designed, like in 1941, and they focused on
3 important things like textiles and food and all those to
4 support defense purchasing of those critical commodities.

5 What I would suggest is either you amend that to
6 include pharmaceuticals and medicines, or you address the
7 loophole that I mentioned, and once you can do that -- and
8 this is not an original idea from me. The API Innovation
9 Center pointed this out about 18 months ago. So what I
10 would say is once we fix that through legislation, a lot of
11 the other things that you are suggesting can more easily
12 occur without challenges in court.

13 Senator Scott: Okay. So if we want to solve this,
14 name the list. We have got to change that court case, and
15 that is one.

16 Colonel Suarez: Yeah, so that is one. The second one
17 is I would encourage the DoD to continue monitoring this
18 quality assessment pilot so that we can better understand
19 that health care systems actually can buy low-cost drugs
20 that are of high quality, because some initial data shows
21 that that is very possible. And then the third thing --

22 Senator Scott: We do it in the private sector every
23 day, so it is all possible.

24 Colonel Suarez: Yes. Yes, sir.

25 Senator Scott: We would not have to have a study. I

1 mean, that is pretty basic stuff.

2 Colonel Suarez: The study actually generates the data
3 that is irrefutable that you could use to justify the
4 decisions. So yes, sir.

5 Senator Scott: We do it every day, because we like our
6 products to work. Every manufacturing company buys based on
7 quality, because it likes their end product to work.

8 Colonel Suarez: Yes, in normal markets you are
9 absolutely correct, sir. That is how normal markets work.
10 Unfortunately, in the pharmaceutical industry that has not
11 been the standard.

12 Senator Scott: Because we did not do any testing.

13 Colonel Suarez: No. It is not that we did not do any
14 testing. It is that the regulatory agency had a very
15 difficult time, as we transitioned our manufacturing over to
16 Asia, mostly India and China, we lost an ability to actually
17 regulate and inspect those manufacturing plants.

18 Senator Scott: Yeah, but we can inspect it afterwards.

19 Colonel Suarez: Right. But the problem is we have
20 such a big backlog right now, and now when they are checking
21 these facilities they are finding egregious problems. And
22 that is why some of those plants are shutting down as they
23 remediate those problems, and thus that increases more drug
24 shortages. And that is part of what we are seeing right
25 now.

1 Senator Scott: Okay. So we have got the court case,
2 assess, what else?

3 Colonel Suarez: And then I think really provide
4 incentives to industry to domestically manufacture more
5 essential medicines here, not only the finished product, the
6 API, and the key starting materials.

7 Senator Scott: Well, I think it will happen, except
8 for what Dr. Barber is talking about. I mean, some things
9 are going to be so small you cannot do it. But there is
10 enough money, if it is big enough, right.

11 Colonel Suarez: Correct.

12 Senator Scott: If we say we are going to have a
13 domestic product, we can do it. I do not disagree with what
14 you are saying. There are going to be some markets that are
15 not going to be big enough, and this is going to be cheaper.
16 And there are two options. One, pay somebody to do it, like
17 what you said, or do it ourselves.

18 Colonel Suarez: May I add one other thing, too? There
19 are some really good initiatives that are happening in the
20 United States right now, for example, in Senator Kaine's
21 state, for example, with Civica RX, a public benefit
22 corporation, working with Phlow and AMPAC, where they are
23 actually going after these most essential medicines. That
24 is a model that actually could be expanded across the
25 country to address those critical, essential, low-cost

1 generic medicines.

2 So I think we are starting to see more and more
3 examples like what we see in the commonwealth of Virginia
4 that could actually help correct the market over time, so
5 that we can actually address these critical risks.

6 Senator Scott: Thank you.

7 Senator Warren: Good. Thank you. Dr. Barber?

8 Dr. Barber: It was just to say that in terms of market
9 share, DoD's fund really is quite, quite low. I mean, \$7
10 billion is not very much in multinational corporation terms,
11 in terms of global markets. So it really is a drop in the
12 bucket, and the market power just is not there for most
13 products.

14 Senator Scott: I mean, I agree. That makes sense.
15 But you would think if everybody worked together, like if
16 all of our allies were part of this, which we should be able
17 to do, there are still going to be things that make sense,
18 that you cannot get. Somebody is not going to have an
19 incentive because there is not enough profit margin. But if
20 we could get everybody to buy together, we could, in theory.

21 Dr. Barber: A major limitation is the data still is
22 not there in terms of where provenance is, and thank you for
23 bringing up the Acetris case. It is incredibly important,
24 and I would encourage the Committee to reach out to the DLA
25 for legal counsel in terms of kind of what their powers are.

1 I have been doing API research for a long time in terms
2 of capacity building and distribution, and I am heartened
3 that in the last 3 years people have started to take it
4 really seriously in terms of initiatives to not supply. But
5 they are still very ad hoc. There is no systematic mapping.
6 FDA is not doing it. EMA is not doing it. The WHO is not
7 doing it. We have to show data with everyone, with our
8 allies, with all countries. So it has to be an
9 international effort to map how many factors are making a
10 given drug, where are they, what is the capacity. We need
11 to do this systematically. We cannot rely on ad hoc
12 measures.

13 Senator Warren: You know, I very much appreciate that.
14 What I think we are hearing over and over is we need to
15 bring pharmaceutical manufacturing back to the United
16 States, and that it is a critical national defense issue.
17 It is also critically important for the health of our
18 people.

19 And I hear this break into two parts. One is
20 commercial manufacturing, which as you rightly point out, we
21 do not have the right incentives in place. We do not even
22 have the right information in place to require meaningful
23 domestic manufacturing and meaningful insight into the
24 supply chain, to know that we are safe in the drugs that we
25 are getting and into the APIs that we are getting. And that

1 is one part of the problem.

2 And then the other part of the problem is the
3 manufacturing challenges for what are much more modestly
4 scaled projects that we are going to have to move to
5 military manufacturing. Otherwise, we are just not going to
6 get this stuff, or we will pay prices that are so outrageous
7 that we would have been a lot better off -- it would have
8 been cheaper to have built it internally.

9 And so I think those are the two challenges we face,
10 and I know that we both want to work on here.

11 I want to thank all of our witnesses for their
12 testimony today. I also want to thank Jon Clark, Gary
13 Leeling, Noah Sisk, and Katie Magnus, for their work in
14 helping put today's hearing together.

15 We have a letter from the National Association of
16 Manufacturers. They have asked that it be included in the
17 record. Any objection?

18 Without objection on that.

19 [The information follows:]

20 [SUBCOMMITTEE INSERT]

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1 Senator Warren: With that, do we have a period of time
2 for questions? Nope. Alright. We have got 7 days for
3 questions for anybody who wants them. You will have 30 days
4 to reply to those if there are answers that are needed.

5 And with that, this hearing is adjourned. Thank you
6 all.

7 [Whereupon, at 4:10 p.m., the hearing was adjourned.]

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