not think we should. Roger Noriega, with whom I do not always agree on Latin American issues, thinks it is wrong to link the economic support fund issues as well. So people who have strong credentials, if you will, in opposing the International Criminal Court believe that linking these issues in this region is not serving the interests of the United States well at all.

At an appropriate time, in consultation with the chairman of the committee and others, I would like to pursue this matter to see whether my colleagues might agree that we might delink these issues. With that, again, knowing there are other matters that can be dealt with, I won't belabor the point.

I have some further comments I will make, but I will wait for the appropriate time to do that so that my full statement can be read by those who may be interested in this particular proposal.

I yield the floor.

The PRESIDING OFFICER. The Senator from Indiana.

Mr. LUGAR. Mr. President, let me respond briefly to the distinguished Senator from New York. The amendment that was offered by the distinguished Senator from Connecticut, as I indicated before he was on the floor, we were prepared to accept. We presumed there was not Democratic Party opposition to that; there were not members of the committee on the floor. Senator DODD is a member of the committee, and, therefore, we acted in good faith, as we have to. We are trying very hard to proceed amendment by amendment, depending upon Senators to be on the floor, to be represented by their party officials and by their staffs. So I am hopeful the distinguished Senator from New York and the Senator from Connecticut may be able to agree on a course of action, but from our standpoint, we believe the amendment was offered and accepted legitimately and in due course.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mrs. CLINTON. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

Mr. LUGAR. I object.

The PRESIDING OFFICER. Objection is heard.

The clerk will continue calling the roll.

The assistant legislative clerk continued with the call of the roll.

Mr. GREGG. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

## MORNING BUSINESS

Mr. GREGG. Mr. President, I ask unanimous consent that there now be a period for morning business with Senators permitted to speak for up to 10 minutes each. I also ask unanimous consent that I be recognized for 20 minutes as the initial speaker.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senator from New Hampshire is recognized.

## THREAT OF BIOLOGICAL ATTACKS

Mr. GREGG. Mr. President, I appreciate the courtesy of the Members who are in the Chamber and who are dealing with the State Department authorization bill and allowing me to proceed as in morning business as they address the issues surrounding that bill.

I wanted to raise an issue which I believe is of very high significance of how we deal with the threat of biological attacks. This has been an issue I have been involved in for a considerable amount of time, having authored the first bioshield bill as the chairman of the HELP Committee at the time.

Just weeks after September 11, anthrax attacks occurred in Florida, New York, and Washington. They killed five people, and they crippled the mail delivery system in several cities and required a cleanup that cost more than $1 billion. For all that, the President's Commission which just reported on weapons of mass destruction says we were lucky.

We cannot really know whether we were exclusively lucky or whether this was the result of responsible effort to prepare ourselves for the next attack that we have not been attacked again or in a worse way, but the facts remain that the threat continues. The President's Commission makes obvious the finding that biological weapons are cheaper and easier to acquire than nuclear weapons, and they could be even more deadly.

There is no question that if terrorists are able to get their hands on a weaponized biological agent, whether it is anthrax, small pox, botulism, or ebola, they will use it in a place where Americans gather in their daily lives. Whether it is a subway system as occurred in Japan or a building as occurred in the Capitol, it is these types of attacks—biological, chemical, and dirty bombs—that pose the greatest threat to our Nation.

The President's Commission, which released its report last Thursday, exposed the stark reality that our intelligence community may have underestimated the progress of terrorists and others in developing biological weapons. For example, in Afghanistan, investigators found evidence that after the war, al-Qaida had the capability to produce a virulent biological weapon identified only as ''agent X,'' which documents suggest was anthrax.

Much of the information we have on the development of biological weapons by terrorist groups and rogue nations is classified; however, it is no secret that Soviet scientists were working on engineering biological agents before the fall of the Soviet Union, including smallpox engineered to be totally lethal, a hybrid plague that is more resistant to vaccine, and a strain of anthrax resistant to seven different antibodies. Unfortunately, we have no assurance that all of these products which they were trying to develop have been destroyed. We are aware of some rogue countries that developed delivery systems such as anthrax-laced cigarettes and botulism-contaminated beer.

While the President's Commission finds the threat deeply troubling today, they foretell that it will be more tomorrow, when genetics modification techniques will allow creation of even worse biological weapons. These findings underscore that the threat posed to our national security from biological, chemical, radiological, and nuclear weapons is truly real and significant.

Even before the anthrax attacks here, we as a Congress recognized the need to enhance three critical enterprises or sectors in our country to better protect our people from attacks by biological agents: No. 1 the research enterprise, led by NIH and private researchers; No. 2 the biotechnology development and manufacturing sector, particularly vaccines but also other countermeasures such as drugs and devices; and No. 3 the broader health care delivery system, including physicians, hospitals, and public health departments here and abroad.

The first substantial effort, started before the anthrax attacks and completed in 2002, was the Bioterrorism Act of 2002, which dramatically increased funding for the Strategic National Stockpile so that a national pool of countermeasures, including those to protect against smallpox, could be maintained. It also dramatically improved our border protection authorities, particularly for food imports; protected our water supply; dramatically increased oversight of research labs that handled agents that could potentially be used in an attack; and committed substantial new resources to our state public health systems and hospitals to ensure improved surveillance and surge capacity. Institutionally, it also created a number of new Federal authorities to identify and develop and coordinate our response to a threat.

In 2003 and 2004, following the President's call and leadership, we passed the bipartisan Project BioShield Act to confront weaknesses in our ability to have the research enterprise speed results to us and to have FDA speed products to potential victims. Notably, we pre-funded a $5.6 billion account to assure the developers of countermeasures that if they delivered a product that protected this country from a biological attack then the Government would in fact have the resources to purchase that product and recognize their work.

Project BioShield recognized that we had very little on hand to address even

the handful of agents that pose the greatest threat, such as smallpox, anthrax, botulism and plague. As a result, we have made valuable progress.

Our smallpox stockpile has grown from 90,000 doses of smallpox vaccine ready for use in 2001 to 300 million doses today. We have modified vaccinia Ankara, a next-generation smallpox vaccine that promises greater safety, in clinical testing and others in predevelopment. In addition, we have a new oral form of an antiviral drug cidofovir in advanced product development for use in the event of a smallpox attack and to treat the rare complications from the smallpox vaccine.

To combat anthrax, a new recombinant vaccine is in clinical testing and may need fewer doses than the classic vaccine, and the Department of Health and Human Services has contracted with VaxGen to purchase 75 million vaccine doses under BioShield. New anthrax therapies that can neutralize the anthrax toxin are also being developed, such as monoclonal and polyclonal antibodies.

To combat botulism, treatments for the toxin and a vaccine to prevent the disease are in development. And finally for Ebola a new vaccine is in development.

Project BioShield was a good start, but we must do more. As the authors of the Center for Biosecurity report note: The legislation represents a significant step for the government and demonstrates [its] seriousness [but] is only a necessary first step.

We have identified dozens of agents that could be used against our people, yet we still lack vaccines and treatments for some of the gravest biological and chemical threats, such as ricin, plague, and viral hemorrhagic fever. We still lack an antidote to sulfur mustard and nitrogen mustard—and those available for sarin and VX have significant limitations in their practical utility given the speed with which they need to be applied.

We are also not prepared to fight naturally occurring infectious diseases—such as avian flu—that could be equally as deadly and could be weaponized in the future. And experts in HELP testimony, as well as those responding to a comprehensive survey by the University of Pittsburgh Center for Biosecurity, note the increasing threat of new bio-engineered and genetically modified pathogens. A 2003 CIA review confirms that these strains could be ''worse than any disease known to man.'' Many have observed that we in fact need to move beyond the product-by-product and bug-by-bug approach of BioShield and address solutions more comprehensively and innovatively.

And we have seen a very anemic response within the research and manufacturing sectors to engage in biodefense work. Fewer than 100 companies have come forward with even a modest interest in developing countermeasures for bioterrorism and other agents. The profile of these companies is in many ways positive—they are entrepreneurial, often have crucial insights into a bioterrorism agent or product, can move quickly, and many have strong venture capital connections. However, in other critical ways they lack the ability in our current environment to deliver a finished, effective product to potential victims. These same companies tend to be small, often work on only a single product, rarely have the capital required to bring a product to market, and typically have limited ability to manufacture a product at the level and with the speed required to respond fully to an emergency. BioShield has done little to address these latter concerns.

The President's Commission stated that to combat this continuing threat, the Intelligence community, and the government as a whole, needs to approach the problem with a new urgency and new strategies. We are in fact pushing our luck.

This is precisely why BioShield II—a bill that I introduced as part of S. 3—is critical to our efforts in the war against terrorism. S. 3 clearly indicates that the Senate Republican leadership puts a very high priority on invigorating our biodefense capability. The people and 10 organizations that will be on the front lines of national defense will no longer be just traditional defense industries—providing arms and artillery—but will now include biomedical research and biotechnology manufacturing sectors, as well as health care delivery systems.

Building this biodefense sector is the first step in winning what could be the arms race of the 21st century. We must be secure in the ability of this sector to prevent and defend the United States against biological weapons. If we are capable of developing a vaccine or some other treatment that will neutralize the effect of these types of biological agents, including genetically modified pathogens, then they are less likely to be used against us. This same sector must also be positioned to fight new natural threats, such as a pandemic of avian flu. And, as highlighted by a recent GAO report on Anthrax Detection, we need improved detection and testing methods to accurately determine when an agent has been released and when an area has been decontaminated and is safe. Similarly, as the Washington Post helped uncover, BioWatch style technologies need to be dramatically improved, so that we have confidence in the detection of airborne pathogens affecting our key cities. Currently, lab analysis, even when it is correct, requires days to return results on only 10 agents to date.

A range of experts, including researchers, government officials, and manufacturers, told us in hearings that they need greater Federal assistance for them to bear the risk of developing products to counter biological threats or infectious disease that also divert capital away from the development of other important and often more profitable drugs. Many of the measures in BioShield II legislation, including financial incentives, intellectual property protection, and liability protection were recommended during those hearings.

A key point here is that we need to ensure the participation in this enterprise of not just small, fleet, and innovative biotechnology companies. We need to broaden our attention to large, experienced companies, with multiple sources of financing, the ability to manufacture, license, and bring to market a product, and do so on a large scale in an emergency. Additional measures are needed to encourage potential research, manufacturing, and health care delivery partners to commit substantial resources and take the risks necessary to bring innovative new products to market.

The number-one threat cited by experts in our hearings and experts in a range of forums and publications is the almost boundless liability exposure associated with developing these products—and the resulting massive cost of product liability law suits. The unfortunate liability experience of Bayer, manufacturer of Cipro, bears witness to the exposure a biodefense manufacturer faces—and the litigation costs that will be incurred even when, as in the Bayer case, the manufacturer is eventually absolved.

Manufacturers of biodefense countermeasures typically risk exposure to devastating product liability lawsuits to a far greater degree than typical drug companies and for this reason are unlikely to get commercial liability insurance for countermeasure products. There are a number of reasons. For example, as Project BioShield specifically contemplates, such countermeasures may be made available without the usual battery of clinical trials required for other FDA-approved products. Safety and efficacy data often must be derived, for the most part, from animal trials because healthy humans cannot be exposed to toxic agents during testing for obvious reasons.

Further, the scope of distribution of biodefense products and their method of distribution heightens the risk of a lawsuit—even if the product is otherwise safe and effective. For example, when distributed to large numbers of potential victims, perhaps millions of Americans in an emergency, there will inevitably be harm or injuries that occur around the time of the use of the product but that are in fact associated with the inevitable pre-existing health conditions in that large population. Determining the cause of the harm and distinguishing between the product and other factors will be nearly impossible—and yet liability exposure is evident. Methods of distribution in an emergency, perhaps using less trained persons as a last resort, also increase risk of liability.

Large, responsible, successful companies are—without liability protection—

the most likely to remain on the sidelines for fear of risking corporate assets in defending lawsuits. And with other sources of revenue, other successful products, and products generally with higher profit margins, these same companies in fact act prudently in protecting their general corporate assets from unnecessary litigation associated with lower-margin biodefense products.

Even as Government has begun to purchase BioShield countermeasures, the Government's ability to limit liability has significant limitations. Under current law there are only two legal authorities that allow the Federal Government to mitigate the liability concerns of producers of countermeasures other than small pox vaccine.

The first is through Federal indemnification under Public Law 85–804. The second is through designation/certification under the SAFETY Act. Both of these measures are woefully inadequate to address the practical realities of potential litigation facing providers of countermeasures and the fiscal realities facing the Federal Government.

Protection under Public Law 85–804 and its executive order extension to biodefense products is not frequently granted. When it is, the primary limitation is that the administration typically will not address indemnification prior to award of a contract for a countermeasure—unlike the Department of Defense, which typically does address liability earlier in the process. As a result, potential providers must expend resources to compete for a contract that they may have to refuse due to the lack of liability protection. More often companies simply refuse to bid at all due to lack of certainty on the issue of liability. Numerous technical and definitional limitations on the scope of the indemnification also exist—Is the product inherently dangerous? Is it involved in national defense?—not to mention the nature of indemnification may expose the Federal Government to enormous liability exposure as awards and liability is not structured or limited in any way.

The practical utility of SAFETY Act protections to biodefense products is limited. For example, the potential liability of a provider of a vaccine that is administered prior to a bioterror attack is not addressed—leaving producers of vaccines in particular, as they are typically dispensed prior to an attack, at great risk of liability exposure. Protection also requires a burdensome pre-certification process that has not resulted yet in designation of any biotechnology products. Clearly dramatic improvements on this model are required.

The net impact of this atmosphere results in needed countermeasures not being developed and deployed, thereby exposing the economy, and the Nation as a whole, to far greater potential liability due to the lack of available effective countermeasures in the event of attack. Either way, the Federal Government is likely to bear both the human and financial cost of such an attack as it did on September 11th. But by failing to account for these costs before an attack, countermeasures will not be developed and the Nation will be more exposed to attack, costing America both lives and economic stability.

S. 3, which contains liability protections based on the SAFETY Act, attempts to address these liability concerns not only for terrorism, but also countermeasures developed and deployed to protect the Nation against naturally occurring epidemics such as SARS and pandemics such as Avian influenza. Further, liability protections would be extended to ensure that those delivering health care in an emergency, including biodefense products, receive due protection for 19 stepping up and protecting our country when it is under attack. Further, S. 3 puts some limits on the almost boundless liability exposure.

The second most significant barrier to investment in biodefense technology, according to experts testifying before the HELP committee and other public documents is the failure of current intellectual property law to adequately recognize and protect a researcher or manufacturer's investment in a technology.

The current law mechanism for this involves a combination of patent term extensions and grants of market exclusivity for a product, which permit a patent term essentially to be extended to compensate for periods of time while a countermeasure is in the regulatory review or other process.

Under current law, there are several arbitrary limits placed on the duration and nature of the patent extensions that may be granted on a pharmaceutical product. First, the total effective period of the patent from the date the drug is approved until the patent expires cannot exceed 14 years. Second, no patent extension can exceed 5 years. In addition, only partial credit for a patent extension is granted for the lengthy time the product undergoes research and development before an application is reviewed by the FDA. S. 3 would create a patent term extension authority that is not subject to these arbitrary limits. This type of incentive is also important to recoup some of the innovator or manufacturer's investment in developing the product and for diverting resources from manufacturing other more profitable drugs.

As an alternative, S. 3 provides a second type of patent provision to permit the Government to reward manufacturers who work to develop a new countermeasure use from an existing product or technology during an emergency. This provision could, for example, have been useful with the drug Cipro, used as a therapeutic for a number of reasons, but at that time not otherwise studied for use as a treatment for anthrax exposure. During the anthrax attacks, the government asked the company to step forward—the company responded by researching and developing considerable evidence that their product was indeed safe and effective for treatment following anthrax exposure. Under current law, Americans can only rely on the unselfish generosity of a company to expend these resources to provide the safety and effectiveness data we need. Under my legislation, depending on circumstances, additional incentives involving market exclusivity could be granted for up to two years for the product that was used as a countermeasure. This is an important distinction from the so-called ''wild card'' exclusivity idea, which would allow a company to extend the patent protection of a different product as a reward for stepping forward. Again, this type of incentive will encourage manufacturers to step forward in a crisis and will help them recoup their losses from diverting their research and manufacturing efforts from more profitable products.

We've heard resoundingly that our research, manufacturing, and health care delivery sectors need reasonable assurances that a market for these products will in fact exist should they invest the resources necessary to fully develop them. Under the BioShield approach the manufacturer takes the gamble for product development—the government as the sole purchaser needs to be a reliable partner. I look forward to continuing to discuss viable approaches in this area. In my view, however, it is not politically viable to have that basket of options or incentives include ''wild-card'' exclusivity—or the ability to apply a patent extension or market exclusivity to any product in a company's portfolio, regardless of whether it has any use for biodefense purposes. Today, politically, the reality is that this approach is not sustainable—even if it would serve as a powerful incentive to companies to step up and deliver much-needed biodefense products.

The role of the government in facilitating research, development, and delivery of biodefense products can be great. Unfortunately, all too often, government gets in the way. Accordingly, S. 3 also contains important regulatory reform initiatives for protecting Americans against bioterrorism. First, it has provisions that will improve the international harmonization of U.S. Food and Drug Administration regulations with those of the regulatory bodies of our allies in Europe, Canada, and other developed countries. This will help facilitate the development and approval of biodefense products, and will reduce the costs of regulation by the United States and these countries of biodefense countermeasures such as drugs, vaccines and medical devices. Streamlining and making truly effective the regulatory approaches from these developed countries will also assure the continued safety and effectiveness of these medical countermeasures. S. 3

also requires additional reviews by experts on how to improve regulation of these products.

Second, the bill includes important provisions to assure uniformity throughout the United States of biodefense product labeling and other FDA-regulatory requirements. We urgently need this provision to respond in a uniform and united way to a potential bioterrorist attack or other deadly epidemic.

Dramatically conflicting or confusing state and local labeling and composition requirements will limit the ability of Americans across the country to respond adequately and quickly. It is important to note that the provision includes language for exempting purely local matters such as pharmacy practice laws from national uniformity requirements and unique local conditions.

The Bioterror Act of 2002 took significant steps forward to address public health infrastructure needs of the country. BioShield II builds on these authorities in an effort to prioritize resources to those areas faced with the greatest threat—to build the technical expertise of the federal workforce, particularly at our premier biomedical and health organizations at NIH, FDA, and CDC—and to build private sector response capacity in various private-public arrangements designed to have credentialed, expert, and trained teams on hand to respond quickly to a crisis. Surveillance authorities here and abroad also need to be strengthened and developed—using innovative private sector analysis of prescription drug, hospital emergency room and doctor visits and other ''leading indicators.'' In short, as Richard Falkenrath of the Brookings Institution notes, ''there's no area of homeland security in which the administration has made more progress than bioterrorism, and none where we have further to go. But, it is critical to agree with Elin Gursky with the Anser Institute for Homeland Security, ''This problem won't be solved by money alone.''

We have an obligation to be prepared for the worst threat. Maybe that ''next'' attack will never come. Or maybe it will come tomorrow.

We can't know where or when it will come or what our enemies will try to do. We have to be prepared for all possibilities. Therefore, we have to have a vibrant and strong biotechnical industry, a biomedical industry, and an atmosphere here in the Federal Government which encourages the development of the vaccines and other antibodies which will allow us to address these type of threats.

I yield the floor.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Ms. STABENOW. Mr. President, I ask unanimous consent that the order for the quorum call be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

## FOREIGN RELATIONS AUTHORIZATION ACT, FISCAL YEARS 2006 AND 2007—Continued

Ms. STABENOW. Mr. President, I rise today to speak about an amendment my colleague Senator LINDSEY GRAHAM and I have submitted that would create a special trade prosecutor within the Office of the U.S. Trade Representative.

It is my understanding, working with our leader and the chairman of the Finance Committee, that we are not going to proceed with this amendment and instead will be entering into a colloquy with the chairman of the Finance Committee about his willingness to work with us to add language to create a special trade prosecutor on appropriate legislation coming to the Finance Committee to reauthorize trade laws. We look forward to working with him. I look forward to the colloquy we will be submitting for the RECORD shortly.

I thought it was important to be able to speak about this issue for a moment because I know there are many of us on both sides of the aisle who are deeply concerned about what is happening as it relates to unfair trade practices by other countries. We want to work together on a bipartisan basis in order to address this, and address this as quickly as possible. That is why I am so pleased Senator GRAHAM has joined with me as an author of this amendment. We also have a separate bill as well to do the same thing. We look forward to working with the Finance Committee in order to be able to create the prosecutor and to include legislation in a future bill coming to the Senate.

This amendment is based on the concept by Senator BAYH from Indiana. I thank him for being a serious and thoughtful voice in this debate, for his ongoing advocacy, and for providing the Senate with solutions to fix our growing trade deficit. I congratulate Senator BAYH as well.

This amendment would create a special trade prosecutor appointed by the President and confirmed by the Senate with authority to ensure compliance with trade agreements and to protect our manufacturers as well as our farmers against unfair trade practices. This prosecutor will have the authority to investigate and recommend the prosecution of cases before the WTO, as well as those under trade agreements to which the United States is a party.

Currently, we have an executive branch that is organized in such a way as to make prosecution of unfair trade cases unlikely, at best. This trade prosecutor would allow us to fix that. Coupled with the fact that our domestic manufacturing base has eroded due to unfair trade practices, and we have put our manufacturers and others in our economy in an impossible situation, we are asking our U.S. Trade Representative to do too much and the office is not able to deliver. We ask that they negotiate trade agreements with foreign nations at one moment and then turn around and enforce agreements the next, all without damaging the ability of the United States to negotiate the next trade deal. It is not working. While significant portions of our trade imbalances are not caused by lax enforcement, many of them are.

In February, the Department of Commerce reported that the merchandise trade deficit reached a record level of $666.2 billion in 2004, a 21.7-percent increase since 2003. That translates into job loss. The aggregate U.S. trade deficit, which includes both goods and services, was $617.7 billion dollars, a 24-percent increase over 2003. We have many trading partners that fulfill their obligations under our agreements, but we also have many that do not. We should address this problem with a straightforward solution, a special trade prosecutor.

Yesterday, we finally saw a glimmer of hope on the trade front as the administration began the process of imposing import quotas on shirts, trousers, and underwear. But it could have come much sooner if we had someone in the Government whose job it was to look for these violations and to recommend action.

Commerce Secretary Gutierrez, a man whom I respect and strongly supported as Secretary of Commerce, coming from the great State of Michigan, is already having a positive impact. I hope he will pursue this case until our textile industry finally gets the relief it deserves.

That is not enough. There are more U.S. industries facing similar unfair trade practices. We are proposing an institutional change that will allow us to thoroughly and vigorously investigate and prosecute these cases.

For instance, China is a textbook case of how a foreign government has used a network of illegal subsidies and government interventions in order to destroy foreign competition both in the United States as well as in many other countries.

According to the United States-China Economic and Security Commission, these actions have gone virtually unchallenged by the U.S. Government, despite the fact that China's actions are in clear violation of both U.S. trade law and WTO rules.

These anticompetitiveness actions by the Chinese Government include currency manipulation. I am very proud to have been a cosponsor of the amendment that overwhelmingly passed earlier today, bipartisan amendment, to send a very strong message to China regarding the fact we will no longer tolerate the manipulation of their currency. It is causing job loss. It is causing pressure on our American businesses. I am pleased we were able to address that.