S. HRG. 109–210

ROUNDTABLE DISCUSSION: PREPARING A NATIONAL BIODEFENSE: S. 975

HEARING

BEFORE THE

SUBCOMMITTEE ON BIOTERRORISM AND PUBLIC HEALTH PREPAREDNESS

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

ON

EXAMINING S. 975, TO PROVIDE INCENTIVES TO INCREASE RESEARCH BY PRIVATE SECTOR ENTITIES TO DEVELOP MEDICAL COUNTERMEASURES TO PREVENT, DETECT, IDENTIFY, CONTAIN, AND TREAT ILLNESSES, INCLUDING THOSE ASSOCIATED WITH BIOLOGICAL, CHEMICAL, NUCLEAR, OR RADIOLOGICAL WEAPONS ATTACK OR AN INFECTIOUS DISEASE OUTBREAK

JULY 21, 2005

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C O N T E N T S

STATEMENTS

THURSDAY, JULY 21, 2005

ADDITIONAL INFORMATION

ROUNDTABLE DISCUSSION: PREPARING A NATIONAL BIODEFENSE: S. 975

THURSDAY, JULY 21, 2005

U.S. SENATE,
SUBCOMMITTEE ON BIOTERRORISM AND PUBLIC HEALTH PREPAREDNESS, COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:09 a.m., in room 430, Dirksen Senate Office Building, Senator Burr, chairman of the subcommittee, presiding.

Present: Senators Burr, Hatch, Lieberman, and Schumer.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. This hearing will come to order. Senator Lieberman, welcome.

Senator LIEBERMAN. Thank you.

Senator BURR. We also welcome Senators Hatch and Schumer.

At this time I would ask unanimous consent that all members' statements be included in the record, as well as the full statements of today's witnesses be included in the record, and without objection, so ordered.

Again, I would like to thank you and our colleagues, Senator Lieberman, for being here.

This is the second formal Roundtable that we have had, and I am hopeful that we are growing close to the end of a very long process, but one that was needed greatly.

As we begin to examine all the aspects of S. 975, we certainly have the ability to tap the talents and the knowledge of two people who have been extremely engaged in the process, Senator Hatch and Senator Lieberman. For scheduling reasons, Senator Gregg is unable to join us today, but as we stated when we started this process, we had been charged by Senator Enzi to look at all the pieces of legislation that had been introduced as it related specifically to BioShield, to try to figure out what we collectively have learned over the past several years, and to try to make sure that we incorporated all the great ideas that existed not just on the Hill but around the country.

I can tell you that we have exhausted every opportunity to reach out in a public venue, in a private venue, to individuals that we thought had something to contribute. I truly believe that at the end of this process we will have left no stone unturned to try to learn something that possibly we did not know. I am convinced that as

we go through the final pieces, and that is, trying to assemble a piece of legislation, the same individuals will be included in that process. This is not one that will be written in the dark of night or in a closed room. It is one that will be written based upon the input of experts, and as we move along that process, I believe that we will have a bill that addresses the concerns that are expressed in S. 975, the concerns that are expressed by people on the front line, the concerns that every American has about their security and the threat that is out there.

With that, I want to thank Chairman Enzi and Senator Kennedy. Without their cooperation we would not have been able to go through this process, and they have been extremely helpful. Both are unable to be with us today.

For us to move to the next step, it is absolutely vital that we get the insight from you, Senator Lieberman and Senator Hatch, as it relates to the specific pieces of S. 975 that you have focused on and feel passionate about, so that we understand exactly the reasons these things may be assembled or worded in the way that they are.

I know that you said that you would yield to Senator Hatch first because your schedule accommodated. Since he is not here, if we can, we will go ahead with you and we will work out whatever we need to with Orrin when he comes.

STATEMENT OF JOSEPH I. LIEBERMAN, A U.S. SENATOR FROM THE STATE OF CONNECTICUT

Senator LIEBERMAN. Thanks very much, Chairman Burr, and thanks for inviting Senator Hatch and me to testify about some of the key features of S. 975, which he and Senator Brownback and I have introduced, but thanks really more specifically for the sense of urgent leadership you bring to this matter which is urgent; and the question which is how do we best and most quickly protect our people from the bioterrorist threat and from the naturally occurring threat of infectious diseases?

This is no casual matter. You know, you are new here, and I greatly appreciate that you have focused on this and that you have done it with the support of Senator Enzi and Senator Kennedy because, believe me, if there was ever an occasion for bipartisan cooperation, this is it, because we are talking about truly the national defense, national security, national well-being of our people.

I do want to say that my own feeling is that the best way to combat the threat of bioterrorism is to utilize one of America's greatest strengths, which is our innovational and entrepreneurial talent. The BioShield law that was enacted last year takes the first step, but unfortunately, my conclusion is, without additional reforms, companies are not likely to risk their own capital to fund the necessary research, leaving us with a Government funding model that will be expensive, and I am afraid will not produce the results we need.

The concepts in our legislation, S. 975, including tax, intellectual property and liability reforms, we are confident will give us important additional tools to enlist the industry in this vital research. Let me try to briefly elaborate.

BioShield II calls on this innovational spirit that I have talked about. We need to get companies and investors to commit their re-

sources to this effort, and since intentional, maliciously infected infectious disease and naturally occurring infectious disease may have equally devastating effects, the incentives that we are proposing are extended to countermeasures to nature's threats as well. And I include by example pandemic flu, SARS, malaria, and ebola virus.

Just as we in the United States seek to protect ourselves from new infectious disease threats, clearly, less developed nations are trying to eliminate scourges that have restricted their social and economic development for too long now, and BioShield II seeks to inspire innovation on behalf of neglected markets worldwide.

I am glad to see Senator Hatch here. If you have a minute, I will just say a few more words about our bill, and then yield to my very distinguished colleague.

BioShield II proposes that through the mechanism of a contract for a new product with the Department of HHS, companies receive a menu of tax incentives, some for small and others for medium and large companies. BioShield II, again, through this contract method, provides a menu of intellectual property incentives and options that may be appropriate motivators for start-up midstream or successful enterprises to take on these high-risk assignments.

And finally, through the HHS contract, companies may partake, under our legislation, of a selection of liability protections as incentives to the companies to get them involved. We also provide grants to assist small companies with promising technologies that need support while undergoing regulatory approval of a product, and we address public health preparedness in the case of a national medical emergency by consolidating authority at DHS.

Mr. Chairman, the intellectual property provisions that I mentioned above seem to be drawing the most interest, and frankly, the most fire, so I would like to briefly address this concern.

One option we have here, which is to try again urgently to draw the enormous capabilities of our biotech and pharmaceutical industry into providing countermeasures for both maliciously imposed bioterrorist infectious attacks and naturally occurring ones, is to enact what we are calling a patent bonus that a company could apply to a patent in its portfolio in exchange for achieving the goal we have set, which is to protect us from these terrible threats.

Obviously, we should not burden consumers with higher prices for patented products any longer than necessary, but in this legislation, we are raising the question of whether it is necessary to enact the bonus in order to establish a viable biodefense industry. The fact is that the established pharmaceutical companies have a proven record of success in running clinical trials and gaining regulatory approval for their products, which I believe are the safest and most effective in the world. I understand—and opponents of this provision of our measure have said there might be some increase in the cost of prescription drugs if a patent were extended for some period of time—but I think we have to understand exactly what we are proposing and the trade-off that we are suggesting.

If we need a particular drug, a countermeasure to protect ourselves against a bioterror attack or to cure AIDS, or another deadly pathogen, then this cost should be weighed against the devastating

cost if we fail to secure and develop needed medical countermeasures.

Let me give the argument for how this might work in the world we know today. AIDS is costing America $18 billion a year to treat, to identify, all the consequences of it. In fact, the United States is now spending $5 billion additional dollars a year in aid to foreign countries to treat their citizens suffering from AIDS. To state this as a balance, would that be a fair investment for a cure or vaccine that would render that annual expenditure entirely unnecessary? In other words, if in fact the patent bonus results in some prescription drugs costing a little more than they otherwise would for some period of time, you have got to weigh that against the billions of dollars and incalculable benefits from saving people from the pain of AIDS or other illnesses we would cure. Imagine how much suffering would be ended, as well as lives and money saved.

You have to ask, what is it worth to generate a platform technology that would promptly generate vaccines against emerging viruses? What would we spend for new resistance-free antibiotics or truly effective antiviral medications? Each of these discoveries I think shares something in common. They are not products industry seems to be willing to develop right now because their profit is not assured, there is not a clear market, and the cost of product liability or market failure are too high. These companies are not fulfilling the requirements of their shareholders as they see it by participating in these programs to the extent we need them to in today's economic environment.

I want to finally stress this. Under S. 975, BioShield II, these patent extensions, either for newly developed drugs or for existing patents in a company's portfolio, are selectively available only for a limited time, up to 2 years at the discretion of the Secretary of DHHS, and administered at his discretion, and they are not automatic, which is to say they are not awarded unless the patent holder delivers to countermeasure. At some point the Secretary of DHS will say, OK, what you are working on with regard to a countermeasure for a bioterrorist, an anthrax attack or AIDS or the ebola virus or any number of other threats we face, pandemic flu, it looks good enough that we are going to agree that if it works, we will give you this patent extension for 6 months or 3 months, or maybe if it is big enough, 2 years. But you only get the patent bonus if the countermeasure, an effective countermeasure is delivered. Those incentives do not apply to existing entities or patents purchased from any other company after the contract is enforced.

I am going to yield to my colleagues, but I wanted to directly deal with what clearly seems to be the most controversial part of the proposal Senators Hatch, Brownback, and I have made.

Again, Senator Burr, you are a new Senator, but I think you have the potential to make an enormous contribution on a matter of the most urgent national interest. I thank you for your leadership and I look forward to working with you. And with your permission, I would yield to Senator Hatch.

Senator BURR. Absolutely. Welcome, Senator.

OPENING STATEMENT OF SENATOR HATCH

Senator HATCH. Thank you, Senator Burr. I just joined Senator Lieberman in praising you and commending you for taking the lead in this area because you have been very determined, and I think have really been moving forth in ways that are very much appreciated by me and by Senator Lieberman and others as well. Now, I appreciate also Chairman Enzi's dedication to developing the best legislation possible in the area of public health preparedness.

My longstanding concern in this area of bioterrorism has been manifested in this longstanding partnership with Senator Lieberman. We cosponsored bills in the last three Congresses, including our current BioShield II bill, S. 975. So I would also like to take time to acknowledge the contributions of our new third primary partner in this endeavor, Senator Brownback. As you know, I really appreciate working with Senator Lieberman. He is just a terrific Senator and a person who really takes these matters very seriously, and I am grateful to him, and others as well.

I appreciate my good friend, Senator Schumer over there. He picks on me all the time, but other than that—[Laughter.]

Senator LIEBERMAN. Senator Hatch, he is going to do it again today.

Senator HATCH. Is that right?

Senator LIEBERMAN. Yes. He is going to pick on both of us.

Senator SCHUMER. Could the committee pass out Kleenex to everybody, please? [Laughter.]

Senator HATCH. As you know, I have a difficult time defending myself.

Senator SCHUMER. Oh, yes, I see that.

Senator HATCH. I love Chuck, but he is a pain in the neck sometimes.

Senator SCHUMER. And by the way, that is an improvement on what he said a few years ago. [Laughter.]

Senator HATCH. They have been resurrecting that, much to my chagrin, because it was all done in good sport, and you were a very good sport about it, in spite of the dumb questions. [Laughter.] I could not resist. I apologize.

Recently I have been heartened to the call to action so eloquently stated in a major address at Harvard by Senate Majority Leader Frist. Now is the time to couple words with action.

Warning of the threat is critical, but we must take tangible steps to mitigate this great and growing danger while we can. Both Senator Lieberman and I have long recognized that the only sure way for the Senate to pass comprehensive, meaningful bioterrorism legislation is for the Majority Leader to call upon all of the relevant committees of jurisdiction to report legislation by a certain date.

While we applaud the efforts past and present of the HELP Committee, especially the efforts of Senators Gregg, Enzi, Frist, Burr, Lieberman, Brownback, and I think that we need the active involvement of the Finance, Judiciary, Homeland Security and Agriculture Committees, among the others that have jurisdiction of matters we include in our bill, S. 975. I think this is also the case with the Gregg bill, S. 3. In fact, we just passed the renewal of the

PATRIOT Act out of the Judiciary Committee before I came up here.

I have taken note of, and have been disappointed to see, that by and large the private sector pharmaceutical industry has largely voted with their feet or at least their pocketbooks, and chosen not fully to involve themselves in the search for medical countermeasures to bioterror agents and emerging infectious diseases. The potential product liability exposure alone creates a powerful disincentive to private sector involvement in this field. It is no accident that the American vaccine industry has nearly vanished in the wake of enormous product liability concerns, and likely fueled by sometimes overzealous and outright greedy trial lawyers.

I am also disappointed to sense an air of complacency among too many on the Hill and in the administration because the status quo is simply unacceptable. The hard truth is that in the summer of 2000, the Defense Science Board found that we had only one of the 57 diagnostics, drugs and vaccines most needed to respond to a bioterror attack. We now have only 2 of the 57 countermeasures, and this list does not include medicines for genetically engineered or otherwise exotic bioterror agents. This is not only unacceptable, it is potentially very dangerous and deadly.

Unfortunately, it appears it may well take another terrorist threat similar to the anthrax attacks that many people in this room experienced, or a direct threat from an illness like SARS or avian flu before sweeping reforms are adopted by Congress. I think that is pathetic. The Lieberman-Hatch-Brownback BioShield II legislation, S. 975, was developed and refined with input from literally dozens and dozens of experts over a long period of time. It has been criticized by some as being too broad, too sweeping, and too generous in its incentives. Those critics, in my view, are misguided. This is not a threat we can hope to abate by nibbling around the edges.

BioShield I should have taught us that. We have seen what little result we got from a change in a single area. To move from a position of apathy and unpreparedness to a positive or a posture of strength and vigilance will require more than a minor change here or there. That is why S. 975 contains 29 titles and 360 pages.

It is a comprehensive and aggressive strategy of incentives for the development of effective bioterrorism and infectious disease medical countermeasures, as well as addressing other critical issues like command and control, protection of our food and water supplies, and workforce issues.

To those who focus upon and decry certain features of the intellectual property incentive, such as the wild card patent extension, I ask you, how much would you be willing to pay for preventive measures for a threat of agents like the ebola virus?

Furthermore, the cost of these proposed incentives is trivial compared to the cost of bioterror attack or infectious disease outbreak. Moreover, the research that will be done by companies seeking to earn some of these incentives will likely drive all medical research forward and give rise to many ancillary medical benefits for Americans.

I do not believe that it is possible to understate that a crisis is looming, or crises are looming. Although Secretary Leavitt at

Health and Human Services, and Secretary Chertoff at Homeland Security are working tirelessly to improve our readiness, their hands are tied by many of the problems which are addressed in S. 975, that it is not only intentional threats with which we must concern ourselves. Naturally occurring and emerging disease may prove even more dangerous. People are already suffering terribly from dreadful diseases such as AIDS, tuberculosis, antibiotic resistant organisms and hepatitis. These diseases kill millions each year, and with diseases like SARS and the avian flu, there is evidence that things will only get worse unless we take steps to stop them.

We need to establish biodefense, infectious disease and vaccine industries that can develop new diagnostics and therapeutics as threats evolve. We must develop the capabilities to quickly respond to new threats, and to do that, we must remove obstacles to this research.

We also need to broaden the responsibility for developing these countermeasures beyond the Government by increasing private sector incentives. That is where many of the best and brightest work to develop new drugs. We should let industry do what it does best, and that is innovate. And we should make sure that appropriate rewards exist for those who succeed.

Both S. 975 and S. 3 propose bold and innovative incentives to create a viable market for these medical countermeasures. These bills shift the cost and risk of development of these countermeasures to the biotech and pharmaceutical sector in exchange for substantial and appropriate rewards if and only if these companies successfully develop the countermeasures we need to defend ourselves against an attack or outbreak. Companies will be rewarded for success. This is not a Government subsidy for ongoing research. BioShield II is premised on the notion that we should use the biopharma industry to our national advantage.

It is true that our bill contains aggressive R&D tax provisions, strong liability protections, and several IP incentives, but we will not be able to fill the medicine chest with the 57-plus required countermeasures on the cheap. Biopharma industry representatives have repeatedly stated that only if we enact all of the proposed incentives in S. 975, without dilution, do we have the best chance that industry will venture into this area.

We are in the enviable position of being able to learn from the experiences of Canada and China. They paid an extraordinarily high price for their experiences, but they have hopefully learned from their pain. We must not look on in a disinterested fashion and argue that it could never happen to us. Complacency in this area has fatal results. Developing medicines for these emerging pathogens is perhaps the most important step we as Members of Congress can take to protect our citizens. This is as fundamental to our Nation's security as are our law enforcement personnel, metal detectors at airports and a strong well-equipped military. The magnitude of the threat justifies aggressive and innovative incentives.

And I have mentioned that the spinoffs that can come from it are absolutely startling. When we did that little, wee, tiny orphan drug bill, with a cost of $14 or $15 million, it gave incentives to develop orphan drugs for population groups that are less than 200,000 people. At that time I think there were one or two orphan drugs avail-

able and nobody was trying to find answers to these people's difficulties.

Because we did that little bill, gave minimum of incentives, put some prestige in cooperation under that bill, now we have upwards of 300 orphan drugs being developed; and they found by developing the orphan drugs for the benefit of population groups of 200,000 or less, that they have had spinoffs that have turned out to be multibillion dollar spinoffs. And, frankly, they have had research that has gone far beyond because of the incentives we provided in a very modest bill.

BioShield II, S. 975 also seeks to build and maintain a national public health infrastructure to meet future health-related threats, be they conventional weapons like the bombs in the London transit system, biological threats like the anthrax attacks, or emerging diseases like ebola. One key issue is command and control. To be blunt, today, no one is clearly in command of our public health or medical systems in the event of an attack or outbreak, and that issue has to be resolved.

Our bill, S. 975, also focuses on the need to protect our Nation's food and water supply from bioterror and infectious disease threats. My home State of Utah is a rural State, and I appreciate the importance that agriculture plays for both the physical and economic health of this Nation. People often think of biological threats as something more for city dwellers to fear, but people in the country are no better off, particularly if the threat does not strike initially at humans. Hoof and mouth disease, to name just one disease, could devastate ranchers and families and farms. Many of the medical conditions we worry about can affect animals as well as humans. Any student of history knows that medieval chronicles of plague outbreaks often describe the disease's devastating effects on the animal as well as the human population.

Over half of the infectious disease pathogens we fear today, including avian flu, SARS, ebola, Marburg, malaria, Chagas, schistosomiasis, hantavirus and Lyme disease, West Nile virus, affect both humans and animals.

For this reason we must prepare ourselves for threats to our agriculture as well as to our people.

I know that to some it is disturbing that I am talking about the literal destruction of civilization when I describe these threats, but in fact, I am. There is a reason that pestilence is generally considered to be one of the four Horsemen of the Apocalypse, because disease can cause massive terror and destabilize entire nations.

We have been given an opportunity to prepare ourselves to ensure that our Nation and our citizens are as well-positioned as possible to face any medical threats, but this window of opportunity, in my opinion, is closing. Time is slipping away, and I join with my colleagues in urging you to move forward and as quickly and boldly as we can. The stakes are truly that high.

There are a hundred reasons why S. 975 can be criticized as going too far, but the day after the next bioterrorist attack of natural disease outbreak, I bet there will be 535 Members of Congress who will be thinking and saying that we did not go fast or far enough, and I do not want to have to reach that position.

Let me just close again by thanking you personally, Senator Burr. I agree with Senator Lieberman, you are relatively new in the Senate, but you are a serious, reflective, intelligent man who has grabbed this ball, and has spent the hours and hours of time, you and your staff, trying to understand this issue, trying to push it forward. And I, just for one, want to pay my tribute to you and tell you how much I personally appreciate you as a leader in this area. I think you are doing a terrific job, and I just want you to know that all of us who are really concerned about this are wishing for your success, and we intend to help you to have success in this area. I just want to express my gratitude to you, and gratitude to my two staffers.

And again, I apologize to my dear friend, Senator Schumer for taking this long, and also Senator Lieberman, but usually it is Schumer who takes too long.

Senator SCHUMER. You started off on a pretty good track, Orrin. [Laughter.]

Senator BURR. Senator, I thank you for your comments. I think it is safe to say that I share the urgency that both you and Senator Lieberman, as well as others, have on this issue, and the wonderful thing is that we did not start at ground zero in the process because of really the spade work that has been done by both of you and others—Senator Gregg, the interest that Senator Schumer has had in this, Senator Frist has contributed greatly.

Senator HATCH. Mr. Chairman, will you forgive me for having to leave? I have got U.S. Supreme Court-itis on my plate today.

Senator BURR. As long as we can keep Senator Schumer here and leave you out there without him, we are in good shape. [Laughter.]

Senator HATCH. Keep him here as long as you can and ask plenty of questions.

Senator LIEBERMAN. I do want to reassure Senator Hatch that there are countermeasures to U.S. Supreme Court-itis. [Laughter.]

Senator BURR. With that, Senator Schumer.

Senator SCHUMER. Why don't you say that into the microphone? [Laughter.]

Senator HATCH. Schumer is the best.

Senator SCHUMER. Now, don't say—no, no, no. [Laughter.]

Sometimes, Orrin, I think—and this is an ultimate compliment from me. Sometimes I think you have a little Brooklyn in you. [Laughter.]

Senator LIEBERMAN. We promise not to mention that in Utah.

STATEMENT OF CHARLES E. SCHUMER, A U.S. SENATOR FROM THE STATE OF NEW YORK

Senator SCHUMER. Thank you, Mr. Chairman, and I appreciate the opportunity. I will try to be brief here, particularly because Orrin had such a full statement that covered everything several times.

Anyway, I want to thank both Senator Hatch and Senator Lieberman for bringing their ideas to the table, and I could not agree more with the problem and the need to move quickly. That is extremely important. We are not doing enough. We must. And

the efforts of Senator Hatch, Senator Lieberman, yourself, and many others who have been involved are terrific.

But the need to move quickly and strongly does not mean that you let everything go. It does not mean that anything that puts the name BioShield on it is good. And I am worried that the proposal here will be regarded, should it pass, or could be regarded as a boondoggle that helped the pharmaceutical industry more than it helped BioShield and more than it helped protect us from bioterrorism. And I hope that things can be crafted so that the efforts we put into encouraging pharmaceutical companies to get involved in this issue are first directed at real efforts, not at things they would be doing already; and, second, that the amount of compensation we give them is consummate with the amount of effort they are putting in. And that is the problem with this bill.

And, finally, at a time when drug prices are a huge issue, who are we making pay for this? Purchasers of drug prices. It is not the Government. If you went to an economist, they would say, okay, you believe in BioShield and you need to help the pharmaceutical industry with economic incentives, the Government should pay for it. But we are going to choose particular citizens who desperately need a particular drug to subsidize it. Now, that may be the scheme, but if you are going to do that, you ought to be very careful.

So let me just get briefly to the problems I have. The first and most egregious problem is the wild card patent extension. It is a reward available to drug companies which may be as many as 8 years away from completing work on a countermeasure, and it allows companies to extend one patent for up to 2 years. The patent does not have to be related to the countermeasure. My good friend, Orrin Hatch, mentioned orphan drugs. Those are great. The money that was paid went into the drug itself. They weren't to unrelated incentives. But this is any drug the company can make, they can choose it. And then, the amount of compensation they would get is totally unrelated to the countermeasure.

So Merck, for instance, earned $4.5 billion on Zocor. Merck could get a 2-year patent extension worth $9 billion, which could be in compensation for a countermeasure that might be in the tens of millions of dollars. Who would make such a deal? Who would give Merck a 2,000-percent return?

Now, the answer is the Secretary of HHS has the discretion. Well, smell the coffee, my colleagues. The Secretary of HHS has not been a very good guardian of keeping drug prices low. Just look at the prescription drug bill that was passed. Joe and I voted against it. You were not here, Senator Burr. But it had a $200 billion giveaway. In fact, to help the pharmaceutical industries, the prescription drug bill that the President proposed became such a pallid compromise that no one is happy with it. Why are we going to repeat that? And it was the Secretary of HHS who was fully supporting it.

So I do not have much faith in giving unmitigated discretion to the Secretary of HHS. Smart legislation would put limits, would not let Merck choose Zocor for a countermeasure that might only cost tens of millions of dollars and may never come to pass.

My colleague from Connecticut, my good friend—I love him, I revere him—he said we do not give them the extension for any longer than necessary? That is not true. We give it for whatever the Secretary of HHS wants to. And I for one do not have much faith that that will work out. The pharmaceutical industry, when they work against HHS, seems to always get their way. So that is number one.

The second provision goes to something—and where I come from on this, Senator Burr, is along with Senator Gregg, Senator McCain, and Senator Kennedy, we authored the Generic Drug Act, the New Generic Drug Act that passed a couple of years ago and that has kept the price of generics low. So I care a lot about generic drugs. And the second provision allows companies to get years and years of patent time restored far beyond Hatch-Waxman. And, again, the way the countermeasures are defined in this bill, these patent extensions could be granted to blockbuster drugs already on the market, like antidepressants or drugs for stomach disorders.

Take Prevacid. This is a drug to treat ulcers, which could easily be a side effect of treatment with a countermeasure or of people's panic during time of attack. If the company made a slight tweak and got the drug approved as a countermeasure under the definition of this bill, which could fit, they could get 6 more years of patent protection worth $20 billion.

Now, if for whatever political reason somebody wanted to help out the maker of Prevacid, we would allow them to do so. And paid for by whom? Not by the Senate, you know, the taxpayers as a whole, but by just the users of Prevacid. Why is that fair? I know we do not want to pay any more. That is the problem here. Nobody wants to spend more money on this, so let's find another route. But when the drug people, the people who use these drugs find out that they are being taken advantage of to pay for a benefit for the whole society, they are not going to feel too good about it.

What is worse about these patent extensions is because companies can get their entire patent restored after spending years after developing the drug, it actually removes any incentive to bring the drug to market quickly.

Finally, S. 975 includes a provision that would waive the rights of the Government to spur further production of countermeasures in time of crisis. The waiver of the marching rights takes away the ability of the Government to intervene in easily foreseeable situations where a sudden surge in demand for a countermeasure overwhelms the ability of the company holding the patent. In other words, in this one, again, just—I mean, it seems that the pharmaceutical industry has almost written large parts of this bill. We want to give them money in the first part as an incentive to produce a much needed drug because we need the much needed drug. But when it is against their interests to produce the much needed drug, like it was with Cipro a few years ago, then we say we cannot do it.

So it seems somehow in the pantheon of interests here we have it a little backwards. Instead of the need to get drugs out to market quickly when people need them, we take the needs of the pharmaceutical industry first.

So if there are times of national emergency, we cannot let a patent stand in the way of saving American lives. We have to give recompense, no question about it. But we have to do that.

So I think that these provisions are inappropriate for multiple reasons. Without saying anything negative about the need to do something here and about the idea of helping companies, encouraging companies to do it, just make the incentive proportionate to the reward that the society gets. Do not just leave it completely wide open. The reward is disproportionate to the investment put in, very possibly, depending on HHS and what they approve. A drug company that spends tens of millions or hundreds of millions of dollars developing a countermeasure which will already be compensated when the Government purchases the product could receive a multibillion-dollar windfall at the expense of the drug consumer.

Second, they undermine existing patent law, which protects the rights of consumers to affordable pharmaceuticals. We know how much generic drugs save Americans, save the Government in Medicare and Medicaid. It accounts for 50 percent of the country's prescriptions, 10 percent of the cost. Senator Hatch with Henry Waxman 20 years ago did a lot to protect the intellectual property of pharmaceutical companies, and I agree with that. They have to be rewarded. But, again, the reward should be proportionate. It is a balancing test, and the balancing test in this bill is out of whack.

And, after all, as I mentioned earlier, it is not even clear that rewarding brand new products—that we are rewarding the brand new products that address the most dire threats. The definition of countermeasure could refer to many drugs that are already on the market. Again, you say, well, HHS will not do it. They have done other things that are even more egregious. Countermeasures are not only drugs that treat the direct effect of terror attacks; they can refer to drugs that treat secondary consequences of the attacks. So if a new vaccine produces a new negative side effect, I am all for providing appropriate incentives to ensure we have a drug to treat that side effect. But the language here is not drafted narrowly. As it is, we could end up shelling out money for migraine and antidepressant medications that are already on the market.

So, Mr. Chairman, I propose we keep the thrust of BioShield, but that the patent-extending provisions be removed and be replaced with improved procurement procedures, coupled perhaps with some limited liability protections. I strongly believe we can bring companies to the table without needing to throw in unrelated windfalls whose costs cannot be predicted and that restrict the access of the American people to affordable prescription drugs.

The President proposed cutting funding to bioterrorism preparedness grants. We cannot afford to spend billions of dollars that may never, ever lead to the availability of drugs needed to fight bioterrorism when we have not even spent the millions it would take to make sure the existing countermeasures can be delivered effectively. And I look forward to working with you—I am on the Finance and Judiciary Committees, which have some say over different parts of this, but your committee and all the others—to bring an effective bill that does not open the door for all kinds, as I said, of disproportionate reward and even boondoggles.

Senator BURR. Senator Schumer, thank you very much. I feel compelled to give Senator Lieberman a rebuttal, but for the sake of time, if we can, I understand we are targeted to go to the floor with a vote, an up-or-down vote on Judge Dorr at about 10:50, 10:55. It will not be a cloture vote. My hope is that we could spend 15 minutes with some questions and answers if your time accommodates.

Senator SCHUMER. I apologize, Mr. Chairman. I have some guests here in the back. I have to go see them. They have been waiting.

Senator BURR. If Senator Lieberman has got the time, I would like to do that.

Senator LIEBERMAN. I do.

Senator BURR. Senator Schumer, I know that we have not had an active line of communication with your staff, but if you would so accommodate us as we move into these final stages.

Senator SCHUMER. I would love that.

Senator BURR. As I said prior to your appearance, we have not been given a good task, but we have been given an important task, and that is to try to assemble a bill that addresses all the concerns that we have. And those concerns are not limited just to the health concerns of an attack. It is the concerns that you have and others have about how we word it and what we extend.

I will assure you that we will go through every scenario, explore every option. At the end of the day, whether I am trying to sell Joe on something that we have got in the final product or whether I am trying to sell you on something that you swore should not be there, ultimately I have got the responsibility to convince you. In the overall scheme of things, this was the only thing that we could do to accomplish the end goal. And I think that is the degree of detail we have gone into from a standpoint of looking at all of these issues that come up.

Senator SCHUMER. Thank you.

Senator LIEBERMAN. Mr. Chairman, if I can very briefly before Senator Schumer has to leave, I think it is very important that you try to engage us all in this. Look, I don't think any one of us disagrees with this fact. The current BioShield I is not working. And the normal market mechanisms are not working to bring about the countermeasures we need to deal with bioterrorism or infectious diseases. So we have got to enter the market to create new incentives. That is what this bill would do.

I take heart from the fact that Senator Schumer said he believes that there ought to be some liability protections. That is important. The other important part—I think there are three critical parts of S. 975: one is liability; the other is the tax incentives for companies to get involved; and we think the third is patent extension. And, obviously, we disagree but, look, the bottom line here is urgent threats require urgent solutions. And this is an urgent threat that keeps all of us awake at night. And I am just trying to figure out how do we create an adequate incentive to the biopharma industry to get them to put their considerable talent to work to come up with countermeasures. And one idea is to extend the patents that they have only if there is proof that the company has come up with a countermeasure that works. And what is the consequence? Some

people will pay what they are paying now, not more—the patent will be extended. They will pay what they are paying now for whatever the drug is—Zocor, Prevacid, you know, Lipitor or whatever. They will pay what they are paying now for an additional period of time as determined by the Secretary of HHS.

I really urge my friend from New York, maybe there is a way we can work together on some of the language involved here if you are concerned about it—and I hear you—the latitude that we are giving the Secretary of HHS is of concern. We could create clearer lines so that this is a possible incentive to give.

Senator SCHUMER. I have not said that I am against all patent—using the patent system. It may not be my preferred way, but I am willing to have give and take. But at least there have got to be some guards that you do not do $10 million maybe of needed investment for $1 billion of reward.

Senator LIEBERMAN. Senator Burr, blessed are the legislative mediators. [Laughter.]

Senator BURR. Senator, you partially answered my first question, and that was the three areas that you talked about: liability, intellectual property through patent extension, and tax credits, which you highlight in your bill.

I understand you would not have them all in there if you didn't think it was a package that was needed.

Senator LIEBERMAN. Right.

Senator BURR. But could you prioritize those three things for us from a standpoint of your understanding of their importance to accomplish that.

Senator LIEBERMAN. That is harder for me. As you know, we have got an enormous number of incentives—I believe it is 29—of different kinds. So I have tried to prioritize by going to these three. And they affect firms of different sizes. I think the patent extension will probably be much more attractive and hopefully engage the big pharmaceutical companies. I think the tax incentives—we have an R&D limited partnership incentive, a special capital gains rate, and a new market credit for R&D partnership pass-throughs to investors that I think will be particularly appealing to smaller firms. I think the liability protection is going to be important to both large and small firms.

So it is hard for me to choose among those three. I mean, clearly, I hope that we are going to find it possible to develop a consensus around the liability protection and the tax incentives. The patent extension is the most provocative and controversial, but, frankly, it may be the most effective to engender a real response here.

Senator BURR. Do you possibly see a scenario, being empathetic of Senator Schumer's position, where the patent extension for a company might exist only to the Federal purchases for the purposes of a threat situation? I think we are somewhat confident that we are not buying 100 percent of what we need were we to be attacked. A company having the right to come back and sell under BioShield a second or a third time without competition coming in, but they may not hold the patent if it has run out in the general market. Is that a possibility?

Senator LIEBERMAN. Well, that is one of the alternatives that the Secretary of HHS has under the authority we give him in this bill.

I myself am skeptical about whether that will be enough to engender the enormous investment that will be required from the biopharma industry to come up with some of the countermeasures we are talking about. But we should talk more about it. In other words, I do think as provocative as it is—you know, this idea of the patent extension came out of a lot of talks we had, people on my staff and other staffs, justified by the sense of urgency. What could we do to shake this up to get this extraordinary industry with its enormous innovational capacity that—let's be honest about it, it is helping us live longer, better lives. We all criticize the industry, sometimes correctly because we are upset about pricing, for instance. But the fact is that the lives of all of us and our families are being extended by what they are doing. And the fact is they are not getting into this field because the market incentives are not enough for them. That is why we are looking at the patent extension.

Senator BURR. Senator, would you agree that if we found a way to lessen the investment up front—research, development, clinical trials, that whole process—if the capital investment was less on the part of the companies, we can then moderate the back end as it relates to what is needed.

Senator LIEBERMAN. That is an interesting thought. Possible. I mean, I think probably the most—I am not sure what you are thinking about because there is a balance there, and probably the most significant way we could do it is through tax incentives for up-front investments to diminish the impact on a company. And then I suppose you have the latitude to lessen somewhat the incentives further on down.

This is a tough one because we are speculating about what will bring other people into this field that we urgently need them to get into and where what we have tried so far, BioShield I, has clearly not worked. I mean, to some extent we probably—and I know you have—should talk to the people in the industry directly, although I understand that there would be some skepticism about embracing every single word they say about what they need.

Senator BURR. A broader question, and you alluded to this——

Senator LIEBERMAN. Incidentally—excuse me—I know Senator Schumer did not really mean this, but this bill was drafted by my staff and the staffs of Senator Hatch and Senator Brownback. Trust me, the biopharma industry had nothing to do with the drafting of this bill.

I will say that the staff, particularly Chuck Ludlum, who has now retired to go to Senegal, he had a regular daily e-mail list that probably most people in this room and several hundred others were on. So people knew about what we were doing, but the drafting is ours.

Senator BURR. Your bill creates a number of different things and a number of new offices in a number of different agencies. I am going to ask you a question I have asked everybody in the public arena, the private arena.

Senator LIEBERMAN. Sure.

Senator BURR. From a standpoint of bioterrorism and specifically the BioShield effort or biodefense effect, who should be in charge?

Senator LIEBERMAN. Well, ultimately I think the Secretary of HHS has to be in charge. I mean, there are some parts of this that the Department of Homeland Security will have, naturally, and they have got to work together.

I had an interesting conversation with Secretary Chertoff the other day about the extent to which he is now working, he thinks, better and with clearer lines with Secretary Leavitt at HHS. But——

Senator BURR. Would you agree that there needs to be somebody named in charge of this effort?

Senator LIEBERMAN. I do, and particularly insofar as the focus here is on incentivizing the biopharma industry to produce the countermeasures we need to protect the lives of the American people from a bioterrorist attack and infectious diseases. And that certainly seems to me to fall most naturally under the Secretary of Health and Human Services.

Senator BURR. You have been here for several years and are very familiar with HHS and NIH and CDC and how they work. Do we have a cultural problem with what we are trying to do? Do we have a need that may not culturally fit into how those agencies currently operate? Would you like to comment on that?

Senator LIEBERMAN. Well, it may be. I mean, I will say that there is a judgment being made here, the proposal we are making, which is that we are not going to get what we need for our country in terms of meeting this threat with what might be called a kind of big bureaucracy, command and control, frankly, Department of Defense-type system where we are going to buy everything. We think that will not work quickly enough, and it will end up costing us more than it should. And so far the attempt to put into effect in BioShield I has not worked. This is a very different cultural model. You are absolutely right. This is a model that says let's create—let's enter the market, as I have been saying. Let us, through Government, create the incentives for private capital to come in and get this job done. Using private innovation, which is one of the great strengths of our country, and let us get it done at a much lower cost to the taxpayers.

Now, I am not concealing anything here. It could be that one of the costs associated, as I said before, is that some people on certain prescription drugs are going to end up paying the same that they do now, because the patent is going to be extended for 6 months or a year or whatever.

Senator BURR. You surprised me when you said that BioShield has not worked. Most are not as bold to answer that. I think the jury is still out in many people's minds. I would happen to agree with you.

Senator LIEBERMAN. Well, yes, I think maybe I should amend it simply by saying that we do not see it working yet.

Senator BURR. As robustly as had been——

Senator LIEBERMAN. Yes. And I understand, and there are some responses to this in our proposal that some of it seems to be cultural and bureaucratic. At least that is what the people on the outside say. But I think it goes beyond that, that basically, you know, the incentives that we put out, the system we created for the contract and pledged to buy is just not enough.

Senator BURR. In your conversations, would you agree that the procurement process as designed has been a difficult process for individuals who considered entering into BioShield to understand?

Senator LIEBERMAN. Absolutely. That is what we hear. That is what independent reviews of what has happened so far have told us. And that, no matter what else we do, is something that we ought to try to fix. But it also—though this stuff is mostly entrepreneurial, innovational, it could end up being bureaucratic, too. It could end up being slowed up bureaucratically if the system does not change the culture.

Senator BURR. Last question, and then we can both go vote. Given your view of not just your legislation but what we need to accomplish, if you could describe what success would be at the end of this process, what would it be?

Senator LIEBERMAN. Well, it would be a bill, a law that will quickly bring the power of innovation and entrepreneurship of the American biopharma industry to finding countermeasures for bioterrorist attacks and infectious diseases. And I think it has got to include extensions of—liability protection, tax incentives, and, I believe, some kind of patent extension.

You know, Senator Hatch said it. We all live with this fear that everybody can pick away at our proposal. Senators Hatch, Brownback, and I intentionally went out further than conventional legislation, because this is not a conventional threat. And Senator Hatch said it. You can pick away at this now, but God forbid we come to the day when there is a bioterrorist attack or a terrible pandemic flu in this country, 535 Members of Congress are going to say, "Well, why didn't we do something more, quicker?" And so I think what I would say success would be is if we do something more, quickly, than BioShield I.

Senator BURR. Senator, again, I thank you. This morning when I got the e-mail that potentially the Tubes in London had been attacked again, my initial thought was, Boy, this one may be a bio attack. Maybe that means I need to get this bill done. I have been working on this too long. I think that probably went through the minds of a lot of folks who have sat down with your staff, with you, with my staff, who really have conveyed the sense of urgency that they have about the need to get this bill out there, to get BioShield in a functional capacity and to do it quickly.

The amazing thing—and I hope that Senator Schumer's staff will convey this to him—is everybody that I have met with for the past 6 months as it relates to this effort has been incredibly helpful. Even the ones that may have had much different approaches than you or than I might have, they have been very patient to listen to new ideas.

There has not been an entity—and that includes the big pharma, small pharma, bio device world. Nobody seems to have been in for selfish reasons. I think there is a frustration by big pharma, a frustration that is driven by how their businesses are traditionally modeled, and the fact that they have shareholders and the incredible Catch-22 that Sarbanes-Oxley potentially puts them in when they cannot justify to their shareholders anything other than a profitable venture, which means if you have got a choice between sticking in the private marketplace with patented drugs versus

going over here and accepting liability and potentially not knowing what the time line is, and quite honestly in BioShield procurement, not knowing until very late in the process exactly what the dosage procurement is going to be.

Senator LIEBERMAN. Right.

Senator BURR. It makes it pretty tough for a publicly traded CEO. So this is not something that big pharma has been engaged in. The great thing is that we have a very innovative community out there that wants to participate. From a standpoint of myself, I think I agree with you. Our effort is to see how many—big pharma, small pharma, bio, everybody—that we can get involved in this. My hope is that over the next 30 days we will have that blueprint that we can work in a partnership to try to refine and address as many of the issues that we all are passionate about as we possibly can. I thank you.

Senator LIEBERMAN. Thank you, Mr. Chairman. Again, you can really make this happen, and, of course, we start with Senator Frist being focused on this. What my hope would be is that you bring a bill out this fall and we get to passage through the Senate before the end of the year. It is just that urgent.

You know, your reaction to what happened in London today is not a hallucination. I mean, look, we saw what happened in the Japanese underground system some years ago. I remember the 9/11 Commission said that part of why 9/11 happened was a failure of imagination. What they clearly meant is that we could not imagine prior to 9/11 that people would actually do what those fanatics did to us on 9/11. And now we just have to imagine what others like them might try to do and make sure we are ready. That is exactly the mission that you have accepted. I thank you for it, and I pledge my full support to you as you go forward.

Senator BURR. Thank you once again, Senator.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR KENNEDY

I commend Chairman Burr for his leadership on our subcommittee. He has given us an effective start, and I commend him for the impressive pace he has set.

I also commend Chairman Enzi for his leadership and his strong commitment to biodefense issues, as well as two distinguished former chairmen of our committee, Senator Gregg and Senator Hatch.

Senator Gregg moved the first BioShield bill through our committee last year. He is the lead sponsor of one of the bills, S. 3, we are discussing today.

Senator Hatch and Senator Lieberman are the lead sponsors of the proposal, S. 975, and I join in welcoming them to today's discussion.

I look forward to our discussion about the measures we need to take improve our biodefense capability and public preparedness.

The barbaric attacks in London 2 weeks ago remind us again that we're still highly vulnerable to terrorist attacks, and must never relent in our efforts to protect the safety and health of the American people. We're fighting the terrorists overseas, but we can't neglect the real possibility that they can strike us at home again, and we clearly haven't done enough to respond to that threat.

A year ago today, we took a significant step in protecting our citizens by enacting BioShield. This bipartisan legislation moved the ball forward, most significantly by providing dedicated funds to purchase countermeasures, and establishing a process to assure biotech companies and pharmaceutical companies that the Government will purchase the biodefense products they produce if they protect our national security.

I believe additional action is needed. I'm hopeful we can work together to pass a BioShield II bill that will further improve the Nation's ability to respond to a bioterrorist attack.

One goal is to fully engage the biotech and drug industries, which are not yet adequately engaged in the search for vaccines and drugs to keep us safe. In a sense, these industries are like the defense contractors that do an outstanding job in providing equipment and materials needed to protect our security in other ways. We treat these contractors fairly in building up an arsenal of weapons, and we must treat other industries fairly in building up our biodefense arsenals.

One proposal is to offer liability protections to these companies. A case can be made for such protections, coupled with a compensation program to encourage vaccinations against infectious bioterror agents or even pandemic flu. We must be careful not to create broad protections for companies that are negligent, simply because products have value for biodefense. Liability protections are more questionable for products brought to market for a biodefense use that also have a strong commercial use.

On the defense contractor analogy, we should also consider a greater role for the Government in the production of countermeasures using direct Federal funding by contracts or through a

Federal production facility. Tax incentives are an additional idea well-worth considering.

Increased patent protections or extended market exclusivity are less appropriate for products that have a traditional commercial use. The idea of a patent extension on a product unrelated to a countermeasure, as in the so-called "wild card" patent extension, is an unacceptable way of shifting the cost of countermeasures to the health system when current health costs are already unsustainable.

Patent extensions for products that have a strong commercial use, even if they also have a biodefense use, would impose unnecessary costs on the health system. The Government should fund these costs directly, through appropriations, and not shift the costs onto private payers or other Government programs, such as Medicare or Medicaid.

Public health infrastructure is another area that needs our immediate attention and equal priority with the development of countermeasures. Just as we support our armed forces in Iraq, we should support our front line defenses against bioterrorism at home—our public health and medical professionals.

State and local health agencies and laboratories are underfunded, understaffed, and poorly equipped to respond to the threat. Law enforcement officials are worried too—with good reason—that they're not adequately equipped to prevent and respond to terrorism. What good are countermeasures if we don't have the public health capability to detect an attack and administer treatments? We need to do more to protect our citizens.

Information technology is another indispensable part of preparedness. Electronic health records allow real-time tracking of disease outbreaks, so that early responses can be made effectively. Rapid detection of a bioterrorist attack or a new epidemic can mean the difference between a local outbreak and a national disaster.

Our health defenses against biological attacks need to be as strong as our military defenses. The Bioshield Act was a significant step in providing greater protection for Americans, but we obviously have much more work to do. I look forward to working with the committee to strike the right balance.

Senator BURR. The Roundtable is adjourned.

[Whereupon, at 11:10 a.m., the Roundtable was adjourned.]

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