

Witness:

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Testimony

Chuck Ludlam: Answers to Subcommittee Questions
Roundtable: When Terror Strikes – Preparing an Effective and
Immediate Public Health Response
Subcommittee on Bioterrorism and Public Health Preparedness, July 14, 2005

By way of introduction, I have spent the last four years of my public service career on a crusade to highlight the near total lack of preparedness of our nation and the international community to the bioterror and infectious disease threat. I was the principal author of the 2001 Lieberman bioterror bill, the 2002 and 2003 Lieberman-Hatch bioterror bills, and the 2005 Lieberman-Hatch-Brownback bill, BioShield II, S. 975. I was also the principal author of S. 3, the Republican Leadership bill. And I was the principal organizer of an international panel of 600 experts to draft these bills.

Now that I have retired from public service, I am finally free to say what I know to be true: The response of the Administration and, with some notable exceptions, the Congress to these critical challenges has been grossly inadequate. As for the Administration, it has been reported to me that a high-ranking Administration official admitted that it proposed BioShield I solely to protect its right flank when Senator Lieberman was running for President, not as part of a serious bioterror strategy. It's obvious that BioShield I was poorly calculated and the industry response to it has been to yawn. Yet, despite the introduction of S. 3 and S. 975, there is no indication that the Administration will join in the effort to enact them. As for the Senate Democrats, in crafting the four Lieberman bills, and despite extensive efforts, I was never able to recruit a single Democrat to cosponsor these bills. The reason they all give is that "the generics hate it." Finally, in terms of Senator Frist, we've seen bold words, but few discernable actions. He is, of course, the only person who can ensure that the Congress takes up a comprehensive response to these threats. If we fall short in enacting some combination of S. 3 and S. 975, it will be principally his fault.

On the day I retired from public service, June 24, I sent a "parting shot" email to my panel of 600 experts and a copy of it is printed below. It's being made public here for the first time. I am happy for it to serve as my valedictory regarding the quality of my efforts and the Congressional response.

Unfortunately, it may take overriding political considerations to drive consideration of the deadly serious public policy issues addressed in this roundtable. On June 23 Mort Kondracke wrote a prescient article in RollCall entitled, "Avian Flu Could Become Top '08 Issue. Seriously." He accurately quotes me as saying, "You have a fascinating conflation of presidential politics and serious substance at work here. You have three presidential candidates interested in this issue — Frist, Sen. Hillary Rodham Clinton (D-

N.Y.) and Sen. Sam Brownback (R-Kan.), a co-sponsor of the Lieberman bill. [Also, Evan Bayh] Whoever is out in front will look pretty good if the worst happens. Anyone who's behind the curve will look like a dolt. There will be 9/11-style commissions all over the place and hundreds of Richard Clarkes testifying that they warned about what was coming and higher-ups didn't listen." I stand by these words. I am proud to have issued these warnings and provided this leadership.

(1) What additional incentives or other measures will ensure the timely availability of sufficient amounts of effective biodefense medical countermeasures, and is the cost of such incentives acceptable?

The Lieberman-Hatch-Brownback BioShield II legislation, S. 975, was developed with the active assistance of my panel of 600 experts and it reflects a consensus of that group. It proposes in 29 titles and 360 pages a comprehensive and aggressive strategy of incentives for the development of effective bioterrorism and infectious disease medical countermeasures and addresses a host of other critical issues. The cost of the proposed incentives is trivial compared to the cost of a bioterror attack or infectious disease outbreak. If we are hit with a bioterror attack, or a pandemic, and if we have not secured the development of these medical countermeasures, we're likely to see public panic on a scale similar to that depicted in Spielberg's *War of the Worlds*, Camus' *The Plague*, and Bergman's *The Seventh Seal*. We'll be forced to go straight to quarantines, which will be exceedingly ugly. Those enforcing the quarantines might be given "shoot to kill" orders to enforce the quarantine.

Unfortunately, we are almost totally lacking in these medicines. In the summer of 2000 the Defense Science Board found that we had only 1 of the 57 diagnostics, drugs and vaccines most needed to respond to a Bioterror attack. At the time, the Board projected that we'd have 20 of the 57 within 5 years and 34 within 20 years. But, 4 years later, we have only 2 of the 57 countermeasures; we've added a diagnostic for anthrax. At this rate, we won't have 20 countermeasures until 2076 and 34 until 2132. This list doesn't include medicines for bioterror pathogens engineered to be antibiotic resistant, hybrid pathogens (like the Plague-Diphtheria hybrid developed by the Soviet Union), genetically modified pathogens, and a host of other exotic pathogens like autoimmune peptides or antibiotic induced toxins.

To be clear, it makes no sense to focus solely on countermeasures for bioterror pathogens. We know that Mother Nature is a terrorist who will attack even if terrorists don't. We need vastly more effective medicines to cure and prevent AIDS, malaria, TB, and a host of intestinal parasites, naturally occurring antibiotic resistance (where we face a national crisis), and a host of other debilitating diseases, like Hepatitis A, B, and C -- that kill millions each year. In terms of the death toll, this is a moral and practical crisis similar to World War I and II combined, yet the public policy response has been pathetic.

Because the infectious disease threat is evolving, we need to establish biodefense, infectious disease, and vaccine industries able to develop countermeasures, perhaps hundreds of them, as the threat evolves. The Administration's \$5.6 billion budget for

BioShield I is not remotely realistic. The procurement cost for these medicines will run in the many tens of billions of dollars and it'll be worth every penny.

We also need to establish a research tool industry that will give us the power to more quickly develop countermeasures to new threats. Ultimately, this is the only way we can respond to novel pathogens. We need to repeal the NIH Research Tool Guidelines to establish sufficient economics to establish a research tool industry and not divorce it from NIH funded research regarding new tools.

From the industry's point of view, it's obvious that the "markets" for infectious disease products are deeply flawed. I am intimately familiar with the industry viewpoint because I served for 7 1/2 years as the principal lobbyist for the biotechnology industry. For example, I've heard many executives say it'd be "crazy" to engage in research on AIDS because of "forced genericization." BIO and PhRMA played no role in the drafting of the Lieberman bills because their members don't want Congress to enact incentives that would press them to take up research in which they have no interest. Some in the industry have told me to "shut up" about incentives they feel would press them to "risk their company."

They say, "Look what happened to Bayer," which was subject to virtual expropriation of its antibiotic, Cipro, by HHS following the 2001 anthrax attack. In fact, the outrageous actions of HHS in that case have plagued our ability to engage this industry in this research. We must have credible Administration officials state categorically that these Mafioso tactics will never ever be seen again against a company that develops countermeasures for infectious pathogens. The companies must be rewarded, not vilified.

S. 3, and even more so BioShield II, propose bold and innovative incentives to create a viable market for these medical countermeasures. These bills seek to 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. This is no windfall for the industry. Companies are rewarded for success, not subsidized for running their meters. Conveniently, this is the business model the industry prefers; the better companies all believe that is the government funds the research, the companies will receive a cost-plus rate of return, which is totally inadequate to satisfy their investors. Creating a GoCo will definitely end any possibility that we'll be able to recruit the industry to take up this research. In fact, the industry tells me that they'd welcome a GoCo because it'd let the industry off the hook. Adopting a defense contractor model, where the government assumes all the risk as in a "Manhattan" model, has been tried and proven to be the most expensive and least productive way to proceed. S. 3 and BioShield II are premised on the notion that we can and should use the biopharma industry's entrepreneurial culture to our advantage. This is the only approach that might succeed.

The opposition of the generics to the intellectual property incentives in S. 3 and BioShield II constitutes a classic and predictable NIMBY response. Its opposition is based almost entirely on misstatements about the terms of the proposed incentives and

exaggerations about their potential impact on the cost of health care. It is true that there might be some increase in the cost of healthcare if bio/pharma companies assume the risk and expense of this research and successfully develop a high priority new chemical entity that we need to protect ourselves against a bioterror attack or to cure AIDS or another deadly pathogen, but this cost should be weighed against the devastating costs if we fail to secure the develop the needed medical countermeasures. In the end, the Congress must calculate the costs and benefits of the IP incentives, such as it did when it voted to provide patent extensions when biopharma firms secured pediatric labels on pharmaceuticals.

Biopharma industry representatives have told me on innumerable occasions that the "only" compelling and realistic incentives in S. 3 or S. 975 are the IP incentives that the generics oppose. They say that if we enact all of the proposed incentives in S. 3 and S. 975 without dilution, we stand a reasonable chance that we will be able to overcome the deep industry skepticism about this research. It's imperative that we do so. In Monday's Wall Street Journal Retired U.S. Army Major General Phil Russell, a physician who until recently was a senior adviser to HHS on biodefense issues, states, "God, if Merck or Glaxo or Aventis were involved, it would make life infinitely easier. With small companies, you have to watch them like a hawk." If you want the large pharma companies to help us, you have no choice but to enact bold incentives, including IP incentives. If the Congress buckles to the opposition of the generics and fails to include these IP incentives, it is quite likely that the legislation will fail to achieve its objectives in terms of countermeasure development and we will remain vulnerable to catastrophic morbidity and mortality, public panic, and quarantines.

If you interview the officials in Toronto or China about what they experienced with SARS, it'll transform you're approach to this legislation. You'll conclude, as I have, that developing medicines for these pathogens is an unprecedented and overriding national imperative that justifies the most aggressive and innovative incentives. You will brush aside the NIMBY opposition to these measures.

The IP and tax incentives proposed in BioShield II are not, of course, issues pending in the HELP Committee. I have suggested that the HELP Committee report out a bill with the architecture for a comprehensive bill with brackets, each of which would be left blank except to say "Judiciary Committee," "Finance Committee," "Agriculture Committee," etc. (indicating where to insert the contributions of the other committees). This is the only way for the HELP Committee to demonstrate that it supports enactment of a comprehensive bill. S. 3 includes subject matter within the jurisdiction of at least 4 Senate Committees and S. 975 at least 8 committees. Only Senator Frist can bring all the committees together to fashion an appropriately comprehensive bill.

Finally, BioShield II also addresses the entrenched ineffectiveness of the NIH technology transfer program, undoubtedly the most bureaucratic and risk averse program anywhere. It proposes to strengthen the NIH approach to technology partnerships and protect the value of its patents. If this is not done, then essentially nothing that is funded at NIH will be useful at the beside to patients. The academics who receive NIH grants, represented by

AAMC, oppose these reforms because they oppose holding NIH and its grantees accountable for the impact of NIH funded research on "healthcare," but this puts AAMC deeply at odds with the patient groups for whom "healthcare" is the only bottom line. Of course, it was the patient groups, not the academics, who won the doubling of NIH funding. I suggest that the NIH reauthorization be folded into S. 3/S. 975; the two are complementary and interrelated.

(2) What is necessary to build and maintain a robust national public health infrastructure to meet future biodefense requirements?

BioShield II, S. 975, also proposes an effective strategy for building and maintaining a national public health infrastructure to meet future biodefense and infectious disease requirements. One key issue is command and control. To be blunt, today no one is clearly in command in the event of an attack or outbreak. This issue must be resolved by the Senate Homeland Security and HELP Committees. Again, this will only happen if Senator Frist brings the committees together to fashion a comprehensive bill.

(3) What is necessary to protect our food supply and agriculture from biodefense threats?

BioShield II, S. 975, also includes an effective strategy for protecting our food supply and agriculture from bioterror and infectious disease threats. Approximately 60% of the infectious disease pathogens we fear, including Avian Flu, SARS, Ebola, Marburg, Malaria, Chagas, Schistosomiasis, Hantavirus, and Lyme Disease/West Nile Virus, are zoonotic -- they go back and forth between man and animals. Only Senator Frist can ensure that we engage the Senate Agriculture Committee.

Overall, with regard to S. 3 and S. 975, we need to act as if the fate of civilization depended on it, which is a fair characterization of the reality of the situation.

"Parting Shot" Email from Chuck Ludlam to 600 Bioterror and Infectious Disease Experts
(June 24, 2005)

This is my last email to this group. It's now 40 years since my first day as an employee on Capitol Hill. Paula and I leave to start Peace Corps training in Senegal on September 25. I very much appreciate all the kindness that you have shown to me. It's been quite overwhelming. Several hundred of you helped us to write BioShield II.

It is urgent that you maintain very high expectations of Senator Frist and the Administration. The fate of this legislation lies almost entirely in their hands. Senators Lieberman, Hatch, Brownback, Enzi, Burr, and Gregg have provided superb leadership, but there are severe limits on what they can accomplish without the leadership of Senator Frist and the Administration.

Only Senator Frist can bring together all of the Senate Committees with jurisdiction over elements of BioShield II. And nothing will happen until the Administration finally states unequivocally that we need to enact something like BioShield II.

The key problem is jurisdiction. The HELP Committee has limited jurisdiction. Senators Enzi, Burr, and Gregg can only report out a bill covering a few of the subjects in S. 3 and

even fewer from S. 975. I have suggested to the Committee that it report out the architecture of the entire bill, with open brackets to accommodate the contributions of the other committees. This is a way to force Senator Frist to lead. He's given a sensational speech at Harvard on these issues, but it contains nothing about his plans for the legislation. This is odd for a person in his position when he has command of what the Senate will fashion as a response.

I have sent out hundreds of emails to this group. Senator Frist's staff has received them all, and so have about 40 top ranking members of the Administration. We have here a public record of the warnings that are contained in these emails. If they do not heed these warnings, there is no possible excuse.

For anyone who understands the potentially catastrophic consequences of a bioterror attack or infectious disease outbreak, BioShield II is a modest and minimal proposal. Those that seek to cut back on what we're proposed in BioShield II -- particularly the generic pharmaceutical industry and their Senate supporters -- take a terrible risk with the public health. If they succeed in limiting the incentives in BioShield II, they will bear personal and moral responsibility if we experience an attack or outbreak for which we are unprepared. Their Nimby position and reflexive hatred for the pharmaceutical industry put the nation in peril. Given the dire nature of the threats we face, the misrepresentations they have spread about the terms of BioShield II, particularly the Wild Card patent, cannot be excused as routine lobbying hyperbole. It is possible that thousands and millions might die in an infectious disease outbreak. With Avian Flu running at a 55-70% lethality rate, it's possible to see a billion people dying - the lethality rate of the 1918 Flu Pandemic was 1.8% and 20-100 million died.

To those who say that BioShield II and this email are "over the top," I am happy to let history judge. Others can take full responsibility for ignoring the warnings I have published here. They can also take responsibility for the millions who may die if we delay development of an anti-viral that kills the AIDS virus, a malaria vaccine, and a new class of antibiotics. There is simply no price that is too high to pay for the development of these critical medicines. Unfortunately, I expect in Senegal to see many of my villagers die of infectious disease and in every case I will blame the opponents of BioShield II. My only consolation is in knowing that I have done absolutely everything possible to secure the development of these medicines, with no holds barred.

In terms of the Congress and Administration, there is zero political risk from backing an aggressive set of incentives and programs. The only risk is in not taking these threats seriously enough and cutting back on BioShield II. If politicians do not lead, they also will bear personal moral responsibility for our lack of preparedness.

Thank you all again for your support. This is your legislation to win or lose. It's yours to win now. My role is over. I wish you the best and will be forever grateful for your support.

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