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BIOLOGICAL WEAPONS CONVENTION PROTOCOL: STATUS AND IMPLICATIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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CONTENTS

	Page
Hearing held on June 5, 2001	1
Statement of:	
Zelicoff, Alan, senior scientist, nonproliferation initiatives, Sandia National Laboratories; Amy Smithson, senior associate, Henry L. Stimson Center; Barbara Hatch Rosenberg, project director, Chemical/Biological Arms Control, Federation of American Scientists; Gillian R. Woollett, associate vice president, biological and biotechnology, Pharmaceutical Research and Manufacturers of America; and Colonel Robert P. Kadlec, professor of military strategy and operations, National War College	6
Letters, statements, etc., submitted for the record by:	
Kadlec, Colonel Robert P., professor of military strategy and operations, National War College, prepared statement of	57
Rosenberg, Barbara Hatch, project director, Chemical/Biological Arms Control, Federation of American Scientists, prepared statement of	29
Shays, Hon. Christopher, a Representative in Congress from the State of Connecticut:	
Letter dated June 1, 2001	90
Prepared statement of	3
Smithson, Amy, senior associate, Henry L. Stimson Center, prepared statement of	18
Tierney, Hon. John F., a Representative in Congress from the State of Massachusetts, prepared statements of Ambassador Sheaks and Ambassador Mahley	73
Woollett, Gillian R., associate vice president, biological and biotechnology, Pharmaceutical Research and Manufacturers of America, prepared statement of	45
Zelicoff, Alan, senior scientist, nonproliferation initiatives, Sandia National Laboratories, prepared statement of	10

BIOLOGICAL WEAPONS CONVENTION PROTOCOL: STATUS AND IMPLICATIONS

TUESDAY, JUNE 5, 2001

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:05 p.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Putnam, Gilman, Shrock, and Tierney.

Staff present: Larry Halloran, staff director and counsel; R. Nicholas Palarino, senior policy advisor; Jason M. Chung, clerk; Kristin Taylor, intern; and David Rapallo, minority counsel.

Mr. SHAYS. A quorum being present, the Subcommittee on National Security, Veterans Affairs and International Relations hearing, entitled, "Biological Convention Weapons Protocol: Status and Implications," is called to order.

In 1969, the United States unilaterally renounced the use of biological weapons and foreswore all aspects of an offensive bioweapons program. The Soviet Union also claimed no active interest in germ warfare. Based in part on those mutual assurances, rare in the bipolar cold war strategy environment, drafters of the 1972 Biological Weapons Convention [BWC], did not attempt to include verification or enforcement provisions.

But the disclosure of a vast biological arsenal, of a vast Soviet biological arsenal, Iraq's use of prohibited toxic agents against Iran, and the emergence of terrorists eager to inflict mass casualties generated calls to strengthen the BWC. For almost a decade, discussions have been underway among the 159 BWC signatory nations on ways to verify compliance and deter violations.

Consensus on a workable addendum or protocol to the BWC has proven elusive. Negotiators have been frustrated by the inherent difficulty, some would say utter impossibility, of policing the proliferation of nationally occurring organisms and dual-use technologies so easily converted from lawful to lethal purposes. Many doubt arms control principles and regimes—regimens designed to stop missiles will work against microbes. Some believe the proposed protocol will provide little benefit in the fight against biological weapons, while placing an unjustifiable burden solely on those already committed to wage that fight.

Working toward a target, not a deadline, of next November to present a complete protocol to the BWC Review Conference, the ad hoc group of negotiators in Geneva recently began considering proposals to resolve critical and controversial issues: expert controls, facility declaration thresholds, inspection triggers, the extent of on-site activities, and role of enhanced disease surveillance in detecting violations.

As the negotiating intensifies, pressure will build to adopt a protocol, almost any protocol, if only as a symbol of that political will to do something about biological weapons. But against so insidious a threat, against a class of warfare, the BWC itself declares, "repugnant to the conscience of mankind," a symbolic step is no substitute for substantive progress. Settling for symbolism could in fact undermine the political consensus and technical support needed to achieve tangible results.

The previous administration said as much last September in testimony before this subcommittee. Ambassador Donald Mahley, special negotiator for chemical and biological arms control, told us, "the United States will not accept a protocol that undermines rather than strengthens national and international efforts to address the BW threat."

Continuing our oversight of the U.S. approach to this critical issue, we invited the new administration and the panel of distinguished experts to assess the status and implications to the BWC protocol. We ask them to address how the U.S. negotiating position was formulated, how national security data and private property can be protected in any intrusive declaration and inspection regimen, and what additional steps might be proposed to improve BWC implementation.

Yesterday the White House requested more time to finalize a response to our questions. I regretfully in some ways acceded to that request but felt that I would do that.

But we will hear testimony from witnesses who bring a breadth of experience and depth of insight to this discussion. We appreciate their time and their expertise, and we look forward to their testimony.

And I will say that when the administration made the request to defer testifying before this committee, we were going to cancel, and then we realized, certainly we acknowledged the fact that we have an excellent panel. We know that some of you came here to testify, and we thought that it is important that we proceed. So we are happy you are here. We are delighted to have this hearing, very unhappy the administration has once again requested a deferment before this committee.

[The prepared statement of Hon. Christopher Shays follows:]

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Statement of Rep. Christopher Shays
June 5, 2001

In 1969, the United States unilaterally renounced the use of biological weapons and foreswore all aspects of an offensive bio-weapons program. The Soviet Union also claimed no active interest in germ warfare. Based in part on those mutual assurances, rare in the bi-polar Cold War strategic environment, drafters of the 1972 Biological Weapons Convention (BWC) did not attempt to include verification or enforcement provisions.

But the disclosure of a vast Soviet biological arsenal, Iraq's use of prohibited toxic agents against Iran and the emergence of terrorists eager to inflict mass casualties generated calls to strengthen the BWC. For almost a decade, discussions have been underway among the 159 BWC signatory nations on ways to verify compliance and deter violations.

Consensus on a workable addendum, or protocol, to the BWC has proven elusive. Negotiators have been frustrated by the inherent difficulty, some would say utter impossibility, of policing the proliferation of naturally occurring organisms and dual-use technologies so easily converted from lawful to lethal purposes. Many doubt arms control principles and regimes designed to stop missiles will work against microbes. Some believe the proposed protocol would provide little benefit in the fight against biological weapons while placing an unjustifiable burden solely on those already committed to wage that fight.

Working toward a target, not a deadline, of next November to present a completed protocol to the BWC Review Conference, the Ad Hoc Group of negotiators in Geneva recently began considering proposals to resolve critical, and controversial, issues: export controls, facility declaration thresholds, inspection triggers, the extent of on-site activities and role of enhanced disease surveillance in detecting violations.

As the negotiating intensifies, pressure will build to adopt a protocol, almost any protocol, if only as a symbol of the political will to do something about biological weapons. But against so insidious a threat, against a class of warfare the BWC itself declares "repugnant to the conscience of mankind" a symbolic step is no substitute for substantive progress. Settling for symbolism could in fact undermine the political consensus and technical support needed to achieve tangible results.

The previous administration said as much. Last September, in testimony before this Subcommittee, Ambassador Donald Mahley, Special Negotiator for Chemical and Biological Arms Control, told us, "The United States will not accept a Protocol that undermines rather than strengthens national and international efforts to address the BW threat."

Continuing our oversight of the U.S. approach to this crucial issue, we invited the new administration, and a panel of distinguished experts, to assess the status and implications of the BWC protocol. We asked them to address how the U.S. negotiating position was formulated, how national security data and private property can be protected in any intrusive declaration and inspection regime, and what additional steps might be proposed to improve BWC implementation.

Yesterday, the White House requested more time to finalize a response to our questions. I reluctantly acceded to that request.

But we will hear testimony from witnesses who bring a breadth of experience and depth of insight to this discussion. We appreciate their time and their expertise. We look forward to their testimony.

Mr. SHAYS. At this time I'd invite Mr. Putnam, if he has any statement to make, the vice chairman of the committee.

Mr. PUTNAM. Thank you, Mr. Chairman. I appreciate your putting together this hearing and I appreciate the panel that you have assembled coming here today, and eagerly await the White House's response to your request.

Mr. SHAYS. Thank you. Mr. Schrock.

Mr. SCHROCK. Mr. Chairman, I have no formal statement, but I welcome you as well.

Mr. SHAYS. Great. Well, we are about to proceed, and let me just get rid of some technical requirements here. I ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and that the record remain open for 3 days for that purpose. Without objection, so ordered.

I ask further unanimous consent that all witnesses be permitted to include their written statement in the record, and, without objection, so ordered.

We have a panel of five people, and we have been looking forward to hearing from this panel. We have Mr. Alan Zelicoff, senior scientist, Nonproliferations Initiative, Sandia National Laboratories. Did I say that right?

Mr. ZELICOFF. You did, sir.

Mr. SHAYS. And we have Dr. Amy Smithson, senior associate, Henry L. Stimson Center. Where is that?

Ms. SMITHSON. It is here in Washington, DC, sir, at Dupont Circle.

Mr. SHAYS. And Dr. Barbara Hatch Rosenberg, a project director, Chemical/Biological Arms Control, Federation of American Scientists.

And we have Dr. Gillian R. Woollett?

Ms. WOOLLETT. It's Gillian Woollett.

Mr. SHAYS. Gillian Woollett, thank you—with a nice accent. Associate vice president, biological and biotechnology, Pharmaceutical Research and Manufacturers of America.

And Colonel Robert P. Kadlec, professor of military strategy and operations, National War College.

This is our only panel. We have 5 minutes. We are going to roll over. So you have 10 minutes if you need it. Somewhere between 5 and 10 we would like you to finish, and we are ready to go, except we have to swear you in.

You can still see I am unhappy we have one panel instead of two. If you would stand up and raise your right hands, please.

[Witnesses sworn.]

Mr. SHAYS. Note for the record everyone has responded in the affirmative.

We need a little oil for this thing here.

You are on.

STATEMENTS OF ALAN ZELICOFF, SENIOR SCIENTIST, NONPROLIFERATION INITIATIVES, SANDIA NATIONAL LABORATORIES; AMY SMITHSON, SENIOR ASSOCIATE, HENRY L. STIMSON CENTER; BARBARA HATCH ROSENBERG, PROJECT DIRECTOR, CHEMICAL/BIOLOGICAL ARMS CONTROL, FEDERATION OF AMERICAN SCIENTISTS; GILLIAN R. WOOLLETT, ASSOCIATE VICE PRESIDENT, BIOLOGICAL AND BIOTECHNOLOGY, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; AND COLONEL ROBERT P. KADLEC, PROFESSOR OF MILITARY STRATEGY AND OPERATIONS, NATIONAL WAR COLLEGE

Mr. ZELICOFF. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you.

Mr. ZELICOFF. I am honored for this opportunity to address you today, and since your time is precious, I'll briefly fill you in on my background and then get right to the items that you have asked me to address.

My name is Alan Zelicoff. I am a physician and physicist, and I work in the Center for National Security and Arms Control at Sandia National Laboratories, which is one of the three Department of Energy weapons labs, but we're charged with a broad array of tasks addressing national security outside the nuclear realm.

My center, in which I am one of two senior scientists, has had considerable experience in the primary research and development in a wide array of verification technologies for use in most of the existing multilateral and bilateral arms control treaties to which the United States is a signatory. We're also deeply involved in the day-to-day analysis of data of relevance to these treaties, and provide technical support to both the international and national bodies responsible for implementation and monitoring of these treaties.

In particular, Sandia designed and carried out the most extensive of all mock trial inspections for the Biological Weapons Convention, both in the United States and internationally, following its participation in very similar studies that predated the final negotiations and signatures on the Chemical Weapons Convention.

Now, the committee has heard before from Mr. Mahley and others of the very—of the many problematic differences between verification of the Chemical Weapons Convention and putative verification of the Biological Weapons Convention. I'm not going to repeat those very important distinctions as I respond to the committee's charge, but in so doing, I will try to provide you with a technical as opposed to political reference point and I will refer to some of those distinctions that have been made previously.

And, again, I will try to be technical, as I'm quite sure you get more than enough politicized information up here on the Hill, and as a scientist I'll try to endeavor to highlight some objective data and observations that I hope will assist you in your work.

First, the committee asked how the United States developed verification policy for the Biological Weapons Convention. Well, we began well enough and I believe in a highly credible way with a series of surveys of experts to identify the potential unique and problematic aspects of inspections in support of the BWC, followed

then by increasingly sophisticated mock inspection exercises based on questions raised during those surveys.

These exercises were conducted in a variety of facilities, including the manufacturing facility at Department of Defense biological weapons defense laboratory, a university medical school and the most advanced aerosol-biology facility in the United States, and finally at an explosives testing facility, all of which are of potential relevance to the BWC. And this constitutes the entirety of the United States' experience in testing measures such as challenge inspections, compliance assurance, and familiarization visits; in other words, more or less the compendium of all of the approaches that have been advocated for strengthening the BWC. In my technical opinion, these trial inspections constitute as well the entirety of scientifically designed, well-controlled investigations into the utility of various measures done anywhere by anyone.

And here I would like to issue an important caution to the members of the committee. When you hear claims that other trial inspections for the BWC resulted in successful demonstration of such items as managed access, compliance checking, protection of proprietary information, or validation of declarations under the treaty, be just a bit skeptical. To the best of my knowledge, none—and I mean none—of the other mock inspections that have been conducted meet any of those scientific requirements for trial inspections; and none save those—none in the United States, have been published with their methodologies, hypotheses and analyses for all to see.

Trial inspections are very difficult. They are expensive to execute properly, and it is all too easy to conduct a trial and populate it with hand-picked participants to get the answers that one wishes to hear. We can do, and we did do much better than this.

The U.S. trial outcomes, Mr. Chairman, were clear. Only two measures that have been proposed for the BWC, challenge inspections and disease outbreak surveillance and investigation, resulted in information that was useful for monitoring the BWC. The other oft-touted measures, such as declarations checking, resulted in so much ambiguous data that the inspection teams left the sites, convinced that legitimate activities were covers for biological weapons activities.

There is no mystery in this. Most of the activities in the daily work of pharmaceutical and biodefense facilities are indistinguishable from activities that could be prohibited by the BWC. Conversely, illicit work might be done in similar places and is very easily hidden. And our technology, regrettably, at the moment does not provide us with the diagnostic tests that can separate evil intent from legal and perfectly permissible activities.

To be concrete, a random visit to a modern pharmaceutical facility, for example, would be unlikely to uncover prohibited activities, even if they existed, because of the size and multiplicity of processes taking place. Rather, the very acts of genetic engineering, large-scale fermentation, and the entire array of standard operating procedures will meet any expectations in the pre-formed eye of the beholder.

On the other hand, if a specific allegation were to be leveled, for example, production of large quantities of anthrax at a specific

time and place, there is a reasonable chance that the illegal activity would be unveiled, assuming that access was granted in a timely fashion.

Despite these valuable results, the process of policy development within the U.S. Government, protocol negotiations soon faltered. It is, Mr. Chairman, a not very well-kept secret that there was intense friction between the National Security Council and the entirety of the Interagency Working Group on Biological Weapons Control throughout the past 8 years while policy was under development. Essentially, nothing in the way of tangible policy was put forward during this time because one, or at most a few, low-level staffers within the NSC sought to suppress the results of the mock inspections, break interagency consensus on negotiating strategy, and impose an extraordinarily ill-suited vision for the BWC protocol, which was to make it like the chemical weapons protocol.

Nothing could be more wrong-headed, for all of the reasons you heard in last September's testimony, and nothing could be more destructive for the future of the BWC. There is no question that there was a complete absence of serious administration attention to the negotiations taking place in Geneva. Otherwise these grating questions about goals and tactics that haunted all members of the delegation for the past 8 years would have been resolved. That low-level NSC functionaries were able to force gridlock speaks volumes about the lack of leadership for and periodic review of the U.S. negotiating stance.

Now, this brings me to the second question raised by the committee, which is what was the ability—what is the ability of the chairman's text to detect and deter rogue nations' BW activity? The answer is very little, and the reasons are very simple. The vast majority of effort in the chairman's text is directed at routine random visits—primarily in the West, the plurality in the United States—for purposes of checking on declarations of items and stocks which are in and of themselves very fluid. And it was these very types of visits that were simulated in the U.S. trials and that were the source of so much confusion and actual undermining of confidence in compliance during those trials.

Once again, the NSC broke consensus on even the utility of disease monitoring, which was also demonstrated to be an effective measure, which was a most unusual state of affairs, because there was interagency consensus on the utility of disease monitoring and, sadly, abrogation of the usual understanding of the way interagency politics works cost the U.S. delegation any chance of unifying to significantly influence the outcome of debates in Geneva, including in the western group.

Let me be clear. We were forbidden—and I mean forbidden—to present the results of U.S. trial inspections, even after other countries introduced data from scientifically very flawed trials, and a leadership vacuum resulted.

Mr. Chairman, I do not suggest that the U.S. trial inspection work constitutes a significantly large experience to draw final conclusions about measures that may, with further work, be crafted in a way to strengthen the BWC, but the design of these experiments done in the United States is far superior to those done in other countries that reported them in Geneva. Rather, Mr. Chairman,

when combined with the reports of the U.N. Special Commission on inspections of Iraqi BW sites, the analysis of all of this information leads me to question the standard tenets of arms control in the context of biological weapons. Frequent visits to check declarations are not necessarily better than challenge inspections alone. Declaring collections of microorganisms, whose functionality can easily be changed from a predetermined list, is arguably worse than no information at all. Doing something should never be confused with doing something useful.

Verification advocates, especially those in the scientific community such as the Federation of American Scientists, have a responsibility to carefully test these assertions. It is noteworthy that the Congress had sufficient insight to mandate several years ago more trial inspections, yet the administration just past ignored this requirement, almost certainly because BWC verification proponents within the NSC did not want to learn any lessons from those inspections.

But the end result need not be tragic. There are at least two areas where I do believe substantive support to the treaty can be garnered, as well as meet the interests of all States Parties, and that would be technical cooperation in the identification and mitigation of infectious diseases and swift punishment for countries that employ biological weapons resulting in those diseases or support terrorist groups who acquire them.

On rare but important occasions, a network, which I believe would cost only in the range of about $100 million over an entire decade, of disease reporting stations could identify the emergence of unusual symptoms and signs that would raise questions of violation of the biological weapons treaty. There is little doubt that the techniques of modern epidemiology could identify the source of the disease and distinguish between naturally occurring diseases and intentionally introduced diseases.

To conclude, Mr. Chairman, negotiations on a protocol for the BWC have failed to produce a document that strengthens the convention or increases the security of its member States Parties. We must await new technologies in order to verify nonproliferation of biological weapons. Only a political sea change will permit the elimination of some of the controls that currently exist, such as export controls, and I would never advocate that. The current turmoil in Russia makes it unlikely that the largest biological weapons program in the world cannot come under control, protocol or not. But nations of goodwill can immediately address the pervasive problems of infectious disease, which is of concern to all of us, and the BWC provides the best possible forum for meeting that need.

Thank you for your patience, Mr. Chairman.

Mr. SHAYS. Thank you for your very provocative statement.

[The prepared statement of Mr. Zelicoff follows:]

Testimony of Al Zelicoff

Mr. Chairman and members of the Subcommittee:

I am honored by this opportunity to address you today. Since the Committee's time is precious, I will briefly fill you in on my background and then get right to the items you have asked me to address. I work in the Center for National Security and Arms Control at Sandia National Laboratories, one of the 3 Department of Energy weapons laboratories, but charged with a broad list of tasks addressing national security outside the realm of nuclear weapons per se. My Center, in which I am one of two senior scientists, has had considerable experience in the primary research and development of a wide array of verification technologies for use in most of the existing multi-lateral and bilateral arms control treaties to which the United States is a signatory. We are also deeply involved in the day to day analysis of data of relevance to those treaties, and provide technical support to both international and national bodies responsible for the implementation and monitoring of the Chemical Weapons Convention, all nuclear treaties (including the Limited Test Ban Treaty, Threshold Test Ban Treaty, and Comprehensive Test Ban), and the Biological Weapons Convention. In particular, Sandia designed and carried out the most extensive of all of the mock trial inspections for the Biological Weapons Convention, following its participation in similar studies pre-dating the final negotiations and signatures on the Chemical Weapons convention.

The Committee has heard before, from Mr. Mahley and others, of the problematic differences between verification of the Chemical Weapons Convention and putative verification of the Biological Weapons Convention. I will not repeat those important distinctions, but will refer to them in some detail as I respond to the Committee's charge. In so doing, I will try to provide a technical as opposed to a political reference point. I am quite sure you get more than enough politicized information; as a scientist, I will endeavor to highlight some objective data and observations that I hope will assist you in your work.

First, the Committee has asked how the United States developed verification policy for the BWC Protocol.

We began well enough, and I believe in a highly credible way - with a series of surveys of experts to identify potential unique and problematic aspects of inspections in support of the Biological Weapons Convention, followed by increasingly sophisticated mock-inspection exercises based on the questions raised during those surveys. These exercises, conducted at a vaccine manufacturing facility, a Department of Defense biological weapons defense laboratory, a University medical school, the most advanced aerosol-biology

facility in the United States and at an explosives testing facility – all of obvious relevance to any BWC monitoring protocol - constitute the entirety of the US experience in testing measures such as "challenge inspections", "compliance assurance", and "familiarization visits" – in other words, more or less the compendium of approaches advocated for strengthening the Convention by various countries involved in the BWC Protocol negotiations. In my technical opinion, these "trial" inspections constitute as well the entirety of scientifically designed, well-controlled investigations into the utility of various measures done anywhere by anyone. And here I would like to issue a caution: when you hear claims that other "trial inspections" for the BWC resulted in successfully demonstration of items such as "managed access", "compliance checking", "declaration validation" be just a bit skeptical. To the best of my knowledge none – and I mean none – of these so-called mock inspections meet any of the scientific requirements of trial experiments, and none (save some of those that I describe as part of the US Government effort) have been published with their methodologies, hypotheses, and analysis intact for all to see. Trial inspections are difficult, and expensive to execute properly. It is all too easy to construct a trial, and populate it with hand-picked participants, to get the answer one wishes to hear. We can do – and did do – better than this.

The US trials outcomes were clear. Only two measures – challenge inspections and disease outbreak surveillance and investigation – resulted in information that was useful for monitoring or strengthening the BWC. Other oft-touted measures such as "declaration checking" resulted in so much ambiguous data that the inspection teams left the sites convinced that legitimate activities were covers for biological weapons activities. There is no mystery in this: most of the activities in the daily work of pharmaceutical and bio-defense facilities, and even medical school microbiology laboratories are indistinguishable from activities that might be prohibited by the BWC. Conversely, illicit work that might be done in similar places is easily hidden. At the moment, our technology does not provide us with diagnostic tests that can separate evil intent from legal, perfectly permissible processes and procedures except in the case of challenge inspections for a specific set of reasons. To be concrete, a random visit to a modern pharmaceutical facility would be unlikely to uncover prohibited activities even if they existed because of the size and multiplicity of processes taking place; rather, the very acts of genetic engineering, large scale fermentation and the entire array of standard operating procedures will meet any expectations pre-formed in eye of the beholder. On the other hand, if a specific allegation were to be leveled – production of large quantities of anthrax, for example, at a specific place and time – there is reasonable chance that the illegal activity would be unveiled, assuming that access was granted in a timely fashion. Also, the tools of modern epidemiology are such that should an odd disease outbreak take place, it is likely that investigators could (again, with proper access) distinguish between a natural event or one of man-made origin.

Despite these valuable results, the process of policy development within US Government Protocol negotiations soon faltered. It is a not-very-well-kept secret that there was intense friction between the National Security Council and the entirety of the Interagency Working Group on Biological Weapons control throughout the past 8 years while policy was under development. Essentially nothing in the way of tangible policy was put forward during this time, because one or at most a few low level staffers within the NSC sought to suppress the results of the mock inspections, break interagency consensus on negotiating strategy, and impose an extraordinarily ill-suited vision for the BWC Protocol, which was: make it like the Chemical Weapons Convention protocol. Nothing could be more wrong headed for all of the reasons that you have heard in last September's testimony, and nothing could be more destructive for the future of the BWC. There is no question that there was a complete absence of serious Administration attention to the negotiations taking place in Geneva, otherwise the grating questions about goals and tactics that haunted all members of the delegation for all of the past 8 years would have been resolved. That low level NSC functionaries were able to force gridlock speaks volumes about the lack of leadership for and periodic review of the US negotiating stance throughout most of the 1990s.

This brings me to the second question raised by the Committee: what is the ability of the Chairman's Text to detect and deter rogue nation and terrorist BW activity? The answer is: very little, and the reasons are simple. The vast majority of effort envisioned in the Chairman's Text is directed at routine, random visits to sites around the world – most in the West, the plurality in the United States – for purposes of checking on declarations of items and stocks which are in and of themselves highly fluid. It was these very types of visits that were simulated in some of the US trials – three of them in Albuquerque with which I am intimately familiar – and that were the source of confusion and actual *undermining* of confidence in compliance. Challenge inspections can be blocked by a simple majority of States Parties, and there are a series of roadblocks in front of those measures likely to be most fruitful: timely investigation of disease outbreaks. Without unobstructed operation of these items, the real substance of the Text is fatally weakened. It is important to note that the US delegation expended very little capitol in the Geneva debates promoting enhanced disease monitoring for the BWC. And, once again, the NSC broke consensus on even the utility of disease monitoring within the interagency working group – a most unusual state of affairs as long-standing interagency rules specify that the NSC intervenes in policy disputes only when consensus among executive agencies can not be achieved. Sadly, abrogation of this understanding cost the US delegation any chance of unifying to significantly influence the outcome of the debates in Geneva, including those taking place within the Western Group. Most substantively, we were forbidden – yes, forbidden – to present the results of the

US trial inspections even after other countries introduced data from scientifically flawed trials. A leadership vacuum resulted, quickly filled by opinions and beliefs rather than experience and hard-won information. In the end, pro-forma arms control, the least-common denominator in the multi-lateral forum filled the void, and the bulk of the Chairman's text.

Because of its focus on declarations of facilities that would be very unlikely to engage in illegal activities, followed by random visits to those facilities, it is clear that Chairman's text would not improve the verifiability of the BWC. Indeed, the very notion of "verification" became a political stalking horse – instead of substantive issue – for various interests, non-government organizations included, throughout the Geneva process. The US had, at least at one time, a rather clear view of standards for "verification". While no agency will give you a precise definition of the term, I believe it is fair to say that the minimalist notion would include a "more probable than not" standard, i.e. that any measure or set of measures would have to have more than a random level of likelihood to identify non-compliance (or perhaps "militarily significant" non-compliance) before it would meet verification requirements, while at the same time avoiding false accusations or conclusions. Oddly, the meaning of this key concept - "verification" - received almost no attention in Geneva in recent years. In the early portion of the negotiations in 1991 and 1992 and when US policy was less confused, the delegation was able to foster meaningful debate about "verifiability" standards. Indeed, the US position on the need for measures to meet at least *some* substantive standard led to the early "verification experts group" (VEREX) to remove nearly all references to the word "verification" in their final report, and speak instead of measures to "strengthen" the BWC. Subsequent unresolved bickering between the NSC and the rest of the Interagency removed any possibility that the US delegation could continue to advocate scrutiny of proposed BWC measures based on the verification standard – a great loss, and a waste of precious negotiating time. And some groups such as the Federation of American scientists working group on Biological Weapons assert that verification is possible, conveniently ignoring the US government's mock inspection data, while having none of their own to share. Nonetheless, FAS members appear at every negotiating session to conduct seminars on verification for delegates; such is the outcome from failure of the US to guide the formal negotiations based on facts rather than on beliefs.

Mr. Chairman, I do not suggest that the US trial inspection work constitutes a sufficiently large experience to draw final conclusions about measures that may, with further work, be crafted in a way to strengthen the BWC. Rather, when combined with the reports of the United Nations Special Commission (UNSCOM) inspections of Iraqi BW sites, the analysis of this set of information leads me to question the standard tenets of arms control in the context of biological weapons. Frequent visits to check declarations are not necessarily

better than challenge inspections alone. Declaring collections of micro-organisms whose functionality can easily be changed from a pre-determined list is arguably worse than no information at all. Doing *something* should never be confused with doing something *useful*. Verification advocates, especially those in the scientific community have a responsibility to carefully test their assertions. It is noteworthy that the Congress had sufficient insight to mandate several years ago more trial inspections. Yet, the Administration just passed ignored this requirement, almost certainly because BWC verification proponents within the NSC did not want to learn any lessons from such inspections.

But the end result need not be tragic. There are at least two areas where all States Parties share immediate interests: technical co-operation in the identification and mitigation of infectious disease; and swift punishment for countries that employ biological weapons or support terrorist groups that seek to acquire them.

Infectious disease continues to be the leading cause of death and economic loss throughout the world. Tuberculosis (including multi-drug resistant TB), new influenza strains, AIDS, foot-and-mouth disease in animals, and novel hemorrhagic fevers (most of which were unknown until a few years ago) are clear dangers to the vitality of nations, and in some cases their very survival. Most of these diseases can not be treated, only prevented. Yet we have almost no understanding of their sources and mechanisms of spread. The simplest of reporting systems, based in clinics and hospitals around the world and linked through low-speed Internet connections would begin a new era in the control of these scourges. The cost of such a data–sharing system is very modest, but the knowledge gained is actionable and invaluable to all. The States Parties to the BWC should establish this network as a substantive demonstration of the importance of Scientific and Technical exchange, emphasized so strongly in the Convention. The United States would do well to promote and fund a large share of this system, paying for several thousand computers and Internet links in medically under-served areas of the world, and linking in clinics and hospitals in the West as well. The investment, probably in the range of $100 million over a decade, would salvage US credibility in the BW non-proliferation arena, particularly if the Bush Administration abjures support for the Chairman's text.

On rare (but important) occasions, the network would also identify the emergence of unusual disease (unusual, that is, in either scope or symptoms) that may represent either the use of a biological agent for hostile purposes, or an experiment with a weapon gone awry. There is little doubt that the techniques of modern epidemiology could identify the source of the disease, and distinguish between a natural focus and intentional introduction of organisms or toxins.

The negotiations on a Protocol for the BTWC have failed to produce a document that strengthens the Convention or increases the security of its member States Parties. We must await new technologies in order to verify non-proliferation of biological weapons; only a political sea change will permit the elimination of existing (some would say "discriminatory") export controls; and the current turmoil in Russia makes it unlikely that the largest biological weapons program in the world can come under control, Protocol or not. But nations of goodwill can immediately address the pervasive problems of infectious disease, and the BTWC provides the best possible forum for meeting that need.

Thank you Mr. Chairman.

Mr. SHAYS. Ms. Smithson.

Ms. SMITHSON. Given Al's summary of the missteps that have occurred over the past several years—am I not on?

Mr. SHAYS. Yes, you are on. I need you to put the mic in front of you and down a little lower, and you'll be great.

Ms. SMITHSON. Given Al's summary of the missteps over the past few years, what I'd like to do is concentrate for the next few moments on constructive steps forward for the United States. My statement is based largely on the views of over 30 nongovernmental experts as presented in a recent Stimson Center report, "House of Cards." Concerned about the wayward direction of the BWC negotiations and the U.S. Government's rather lackadaisical approach to these talks, the Stimson Center recruited stellar experts from the three types of facilities likely to be monitored by the BWC; namely, research institutes and universities, pharmaceutical and biotechnology companies and defense contracting firms. We asked these experts to brainstorm the vexing technical challenges of BWC monitoring and assembled a fourth group, nicknamed "Inspection Veterans," to cull the technical lessons they that learned from several BWC inspection-like activities, such as the two U.S. BWC trials and the 1992 trilateral agreement inspections, which were aimed at confirming the closure of former Soviet biowarfare facilities.

The academic and industry group experts separately devised their own monitoring strategies that they believed would work reliably and effectively in their respective settings. However, they differed on several important inspection parameters with what is known as the chairman's text. For example, the chairman's text stipulates a four-member team for nonchallenge visits, but academic experts asked for five to seven inspectors; and industry experts, for an even larger team of six to eight. Whereas the chairman's text would authorize just 2 days for nonchallenge visits, the academic group believed that 3 days would probably be needed for large laboratories, and the industry group thought that 5 days would be required at commercial sites.

When addressing the BWC protocol, negotiators in Geneva on May 7th, during the event releasing House of Cards, one of our industry brainstormers, Dr. Steve Projan, who is the Director of Antibacterial Research at Wyeth-Ayerst Research, summed up the inadequacy of the draft protocol's nonchallenge inspection provisions by saying, "four inspectors for 2 days couldn't even get around all the bathrooms at my facility."

Quite frankly, the industry and academic experts were not very impressed with the draft BWC protocol. The chairman's text appears to have bent over backward to minimize the inconvenience and intrusiveness of inspections. While it is important to hold down the burden of inspections, skimping on manpower and time onsite could yield poor results. These experts repeatedly pointed out that while BWC inspectors must be able to detect noncompliance, they must also know compliance when they see it at legitimate facilities. BWC inspections, they said, should not erroneously tar all university laboratories, research institutes, and industry facilities with suspicion that they are somehow operating outside of the law when

inspectors are not present. This can't leave question marks hanging over everyone's head.

Asked to give the draft BWC protocol a grade, another one of our industry experts explained why the industry groups settled on a grade of D. That is really about the worst grade you can get, said Dr. George Pierce, formerly the manager of technology development and engineering for Cytec Industries. He continued to explain that sometimes an F shows a little innovation.

Aside from a BWC protocol that can reliably produce meaningful monitoring results, other programs necessary to grapple with a problem as complex as biological weapons proliferation include, as Dr. Zelicoff has recommended, enhanced global disease surveillance as well as the maintenance of robust intelligence capabilities and defenses, and wisely designed and well-implemented export controls.

I would add to that list cooperative threat reduction program activities to reduce the leakage of weapons know-how and ingredients from the former Soviet Union, over 50 biowarfare facilities involved.

These so-called brain-drain prevention programs are particularly important if former—because if former Soviet bioweaponeers were to succumb to job offers from terrorists or from governments, they could accelerate rudimentary weapons programs into ones capable of mass casualty attacks. An ounce of prevention, via a hefty budget increase for collaborative research grants, could help cut this proliferation problem off at its source.

As for the BWC protocol, the nongovernmental experts that participated in the Stimson Center's brainstorming series would advise the U.S. Government to reject the chairman's text. Any deal is not better than no deal in this case. But they would certainly not advise the U.S. Government to abandon the negotiating process. All four groups of experts recommended additional technical research and field trials to identify and refine the best monitoring procedures for the BWC. For its part, the Pharmaceutical Research and Manufacturers of America long ago offered its expert technical assistance to help with the BWC protocol. But years later, this statement rings empty, since no industry field trials have been held. Therefore, it is incumbent upon the U.S. industry and the U.S. Government to mount good-faith efforts to test BWC monitoring technologies and strategies fully, inviting international observers into this process to inspire confidence that the United States will not desert the negotiations.

Congress should redirect both the executive branch and U.S. industry to waste no time in initiating an earnest search for meaningful, feasible and cost-effective monitoring approaches to the BWC.

Thank you for the invitation, your time, and I look forward to your questions.

Mr. SHAYS. Thank you, Ms. Smithson.

[The prepared statement of Ms. Smithson follows:]

Prepared Statement
Before the House Committee on Government Reform,
Subcommittee on National Security, Veterans Affairs, and International Relations

5 June 2001

Amy E. Smithson, Ph.D.
Director, Chemical and Biological Weapons Nonproliferation Project
Henry L. Stimson Center

For the past several years, one could hardly turn on the evening news or pick up a newspaper without being confronted with a story about germ weapons and the threat they present to the well-being of US soldiers and citizens. For instance, on 15 March 1993 Secretary of State Colin Powell said while serving as the Chairman of the Joint Chiefs of Staff "Of all the various weapons of mass destruction, biological weapons are of the greatest concern to me." Discussion of the bioweapons threat has not been confined to Washington policy makers, however, for even novelists and writers of television and big-screen movies plumbed the topic for its entertainment value. In contrast to all of the talk about the biological weapons threat, the policies and mechanisms to address and reduce this threat rarely made the headlines, in particular the effort that began in 1995 to strengthen the international treaty banning biological weapons. In fact, the negotiations to add a monitoring protocol to the Biological and Toxin Weapons Convention (BWC) were not often broached even in specialized arms control journals. Therefore, I would like to thank the committee for examining the status of these important negotiations and the policies and programs that the US government should pursue to reduce the threat of biological weapons.

In October 1995 and March 1996, the US government sought to inform its position in the nascent BWC protocol negotiations by staging two full-scale trials of techniques that could be used to monitor this treaty. One of these trials was held at a vaccine production facility, the other at a trio of sites in Albuquerque, New Mexico. Though the location of the trials differed, their outcome was roughly the same. The trial inspectors were unable to determine with high confidence whether the facilities concerned were engaged in legitimate activities or might have been the façade for a covert bioweapons program.

Given these results, it would be reasonable to assume that the US government as well as the pharmaceutical industry, which had facilities likely to fall under the umbrella of BWC monitoring, would put forth considerable effort to ascertain the technical feasibility of BWC inspections and the possible costs attendant to such monitoring. However, neither the Executive Branch nor the industry's principal trade association, the Pharmaceutical Research and Manufacturers of America, made any genuine effort to gather additional field data about BWC monitoring technologies and strategies. This inactivity persisted despite the continuation of the BWC protocol negotiations and the 1999 congressional mandate of Public Law 106-113 directing the Executive Branch to conduct trials at a variety of facilities. With only two inchoate data points to go upon, the White House suddenly announced via press release on 27 January 1998 the position of the US government in the protocol negotiations. The new US position, which had much in common with proposals advanced by the British government, was all the more unexpected because of the known split between the White House and the interagency on what the US negotiating posture should be.

The compliance monitoring provisions contained in what is called the "chairman's text" are based in large part upon the British proposals. Ambassador Tibor Toth, the chairman of the Ad Hoc Group charged with crafting a BWC protocol, released his composite text to the delegations in March 2001. If the Ad Hoc Group is to complete its task in time for the Fifth Review Conference of the BWC's membership to be held this November, then very little time remains—just four weeks of negotiation—to revise the chairman's text. Therefore, it is very important to consider whether this monitoring protocol can perform as intended.

A couple of years ago, the Stimson Center grew concerned about the direction that the BWC negotiations were taking and the US government's rather lackadaisical approach to these talks. With a grant provided by the John D. and Catherine T. MacArthur Foundation and supplemental funding from the Ploughshares Fund and Mrs. Margaret Spanel, the Stimson Center's Chemical and Biological Weapons

Nonproliferation Project turned to nongovernmental technical expertise to explore the vexing technical challenges associated with monitoring compliance with the BWC. This task is extremely difficult because nature is the source of the microorganisms that are the basis of biological weapons, and diseases must be studied if cures are to be found for them. Moreover, technical advances have given scientists the ability to engineer new disease strains and to clean, within a matter of minutes, an entire manufacturing facility's fermenters and pipelines. A government set on cheating could use such capabilities to great advantage. In short, those drafting the BWC protocol need to stretch the horizons of monitoring technologies and strategies if they are to succeed in creating a meaningful and feasible protocol.

The Stimson Center recruited its nongovernmental technical experts from the three types of facilities likely to be monitored by the BWC, namely research institutes and universities, pharmaceutical and biotechnology companies, and defense contracting firms. The Stimson Center asked these groups to "brainstorm" the technical aspects of BWC monitoring, showering them with questions to facilitate their discussions. In addition, the Stimson Center assembled a fourth group, nicknamed the "inspection veterans," to impart the lessons they had learned from the US BWC trial and mock inspections, the visits conducted under the 1992 trilateral agreement to confirm the closure of the former Soviet biowarfare program, and United Nations Special Commission on Iraq inspections. The views and recommendations of all four groups of experts are presented in a recent report entitled *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol.*

Two elements are essential to any success in arms control. First, participating nations must have the political will to negotiate, implement fully, and enforce compliance with the accord in question. Second, those charged with implementing the treaty's provisions—the inspectors—must have the technical means to do so reliably and effectively. With political will and a sound technical foundation, arms control can be a valuable mechanism to enhance national and international security. Absent either fundamental pillar, however, arms control can be a hollow endeavor.

As conveners of the brainstorming sessions, the Stimson Center insisted that the assembled experts park political viewpoints at the door and focus solely on the technical aspects of BWC monitoring. Each of the individuals who participated in the Stimson Center's deliberations is considered top experts in their own respective disciplines. For instance, the academic and research institute group included world renown infectious disease epidemiologist Dr. Robert Shope, the director of the Tuberculosis Center at the Public Health Research Institute Dr. Barry Kreiswirth, veterinary pathologist Dr. Corrie Brown, and plant pathologist Dr. Anne Vidaver, among others. The experts from industry had backgrounds in areas such as vaccine development and manufacturing, antibacterial research, and biotechnology product scale-up and development. Members of this group, which had just under 200 years of combined experience, had worked in smaller, niche firms as well as in the large companies of the pharmaceutical and biotechnology industry, such as DuPont Merck Pharmaceutical Company and Celgene Corp.

As they devised their monitoring strategies, both the industry and academic experts turned to the same tools under discussion in the protocol negotiations, such as advance research on facilities to be inspected, visual observation, documentation review, interviews, and sampling and analysis. Both groups specified ways for the inspectors to ratchet up the intensity of monitoring activities so that the inspectors could determine a site's status, similar to what is known in arms control circles as "managed access" inspections, wherein inspectors and host officials work out compromises on the spot to satisfy inspection and host site needs. After the academic and industry experts finished creating their own monitoring strategies, the Stimson staff asked them to estimate how effectively their techniques would work in their respective settings. Academic and research institute experts assigned effectiveness ratings ranging from moderately to highly effective, while the industry experts handed out grades according to the area of the facility the inspectors were monitoring, giving predominately medium and high effectiveness ratings.

Of note, the academic and industry groups pinned their effectiveness assessments to their stipulations about the timeframes governing inspections and the number and caliber of the inspectors deployed. On several important inspection parameters, these experts differed with what is envisioned in the chairman's text. For example, they argued that more than four inspectors would be needed for a non-challenge inspection: Academic experts asked for five to seven inspectors and the industry group for six to eight inspectors, depending on the size and type of site being monitored. In addition, the draft protocol calls for inspectors to remain on-site for just two days in a non-challenge inspection, but the academic group believed that three days would probably be needed for large research laboratories and the industry group thought that five days would be required to determine compliance or non-compliance at commercial sites. To quote Dr. Steve Projan, Director of Antibacterial Research at Wyeth-Ayerst Research, at the release of *House of Cards* to the Ad Hoc Group negotiators in Geneva on May 7th, "four inspectors for two days couldn't even get through all of the bathrooms at my facility."

After devising their own BWC monitoring tools and strategies, the industry and academic experts were asked to evaluate the measures of the draft BWC protocol. Neither group of experts was very impressed with the Ad Hoc Group's work. Industry experts gave the draft BWC protocol a "D" and would have given it an "F," but in the words of Dr. George Pierce, formerly the manager of technology development and engineering for Cytec Industries, the industry experts settled on a "D" "because that's really about the worst grade you can get. Sometimes an 'F' shows a little innovation."

Defense contractors, inspection veterans, academics, and industry experts were united in their belief that additional technical research and field trials, if well designed, would greatly serve the purposes of an eventual BWC protocol. They were not assured that the terms currently proposed for a BWC protocol would work well for either inspectors or host facilities. The chairman's text appears to have bent over backward to minimize the inconvenience and intrusiveness of inspections to host facilities. While it is important to hold down the burden of inspections, skimping on inspection manpower and time on site could yield poor results that the inspected facilities might find more

offensive than full-blown inspections. After all, these experts pointed out repeated that BWC inspections have two major purposes: 1) to ferret out non-compliance, and 2) to demonstrate compliance on the part of legitimate facilities. They wanted to avoid at all costs a regime that erroneously tarred all university laboratories, research institutes, and pharmaceutical, biotechnology, and defense contractor facilities with suspicion that they are somehow operating outside of the law when inspectors are not present.

The committee should be aware that the compliance monitoring aspects of a BWC protocol are being designed to address weapons programs that governments might maintain and therefore may not have much applicability to the problem of terrorist acquisition and use of biological weapons. However, should a BWC protocol also contain measures to strengthen disease surveillance capabilities around the globe, such capabilities would enhance the ability to detect a disease outbreak, whether caused by governmental or terrorist activities or by a natural eruption of disease. Terrorist acquisition and use of germ weapons might be deterred and the prosecution of such activities would certainly be aided if the international community adopted a proposal, championed by Dr. Mathew Meselson and the Harvard-Sussex Project, to criminalize such activities worldwide.

While enhanced disease surveillance and the criminalization of offensive bioweapons activities are certainly efforts that deserve the full support of the US government, these activities alone are not sufficient to grapple with a problem as complex as biological weapons proliferation. Other advisable endeavors include the maintenance of robust intelligence capabilities, wisely designed and well implemented export controls, and a variety of Cooperative Threat Reduction Program activities to reduce the leakage of weapons know-how and ingredients from over fifty former Soviet bioweapons facilities.

These so-called brain drain prevention programs are particularly important because if former Soviet bioweaponeers were to succumb to job offers from sub-national actors or from governments, they could accelerate rudimentary weapons programs into ones capable of mass casualty attacks. Not only could former Soviet scientists tutor

terrorists and government-employed scientists in the technical arcana needed to keep lethal microbes alive in a suspended aerosol of fine particles, they could hand over seed cultures of contagious diseases that obviate the need for effective aerosol distribution. An ounce of prevention via a hefty budget increase for collaborative research grant programs such as those operated by the International Science and Technology Center could help cut this proliferation problem off at its source. Other Cooperative Threat Reduction Program activities, such as those stiffening security at the bioweapons institutes, should also be fully funded.

With regard to a prospective BWC protocol, the more than thirty nongovernmental technical experts whose views are presented in *House of Cards* would advise the Bush administration to reject the chairman's text, but not to abandon the BWC protocol negotiations. The US government cannot continue to hide behind rhetoric about how serious the bioweapons threat is and how vital the BWC is to address that threat while simultaneously doing little to see that the treaty's prohibitions are policed and upheld. For its part, the Pharmaceutical Research and Manufacturers of America long ago declared its willingness to "offer expert assistance to the US Government to help ensure that any Compliance Protocol to the Biological Weapons Convention is scientifically and technically sound." Years later, this statement rings empty since there have been no industry field trials of prospective monitoring procedures. In *House of Cards*, technical experts from the pharmaceutical and biotechnology industries charted a course for BWC monitoring that they believe could earn industry-wide support. Therefore, it is incumbent upon both US industry and the US government to mount good faith efforts to test fully the assorted permutations of BWC monitoring technologies and strategies, inviting international observers into this process to breed confidence that the United States has not ducked out of the BWC protocol negotiations.

Congress should encourage both the Executive Branch and US industry to waste no time in initiating an earnest search for meaningful, feasible, and cost-effective monitoring approaches to the BWC. Surely, US ingenuity and technical prowess can propel a monitoring regime that is capable of detecting the type of activities governments

would undertake to unleash diseases as weapons of war. Washington must not desert the effort to create an effective BWC monitoring protocol because only when nations that violate the BWC's prohibitions can be identified is it possible to mobilize the international community to take punitive action against them.

Mr. SHAYS. Dr. Rosenberg.

Ms. ROSENBERG. I want to thank you for the opportunity to speak here for the many experts outside of government who support the rapid completion of a protocol to strengthen the Biological Weapons Convention. I chair the Federation of American Scientists Working Group on Biological Weapons, a group of professionals who have broad expertise, who volunteer their efforts in the hope of contributing to the control of a looming long-term global threat that is increasing every day along with the explosive growth of knowledge in bioscience and technology.

My working group has monitored the course of the Biological Weapons Convention and contributed to every effort to strengthen it for more than 12 years. We have conducted trial inspections and held in-depth discussions with inspectors and inspection agencies. We've contributed nearly 50 reports and working papers on technical issues to the protocol negotiations and have organized many seminars for negotiators in Geneva. We've always worked closely with industry and have issued two joint papers with representatives of the Pharmaceutical Research and Manufacturers of America.

I want to start by making sure that a central point is absolutely clear. We are not here to debate whether the chairman's text for the protocol can be relied upon to detect violations of the Biological Weapons Convention. In a situation like this one, where there are similarities between legitimate and illegitimate activities, no protocol or any other mechanism can do that. Finding smoking guns is not what the protocol is about and not what negotiators have ever aimed for. The United States and all the other parties knew this before the negotiations started—it started. They knew it when they studied the feasibility of verifying the convention and issued a positive report. It would be disingenuous to beat that dead horse now.

Rather, the objective of the protocol is confidence building and transparency. Let me explain for a moment what transparency means in this context. Novices tend to suppose that it would require divulging exactly what is going on at an installation. That is nonsense. Experienced technical experts can judge from the scale, the layout, the type of equipment present, the ability to prevent the escape of dangerous agents and such factors, that can judge from these whether these capabilities match the alleged peaceful purpose of an installation and its role, if any, in civil society. Rapid cleanup of an installation before the arrival of inspectors is almost irrelevant. It might even provide a clue in itself. Factors like these were the ones that allowed UNSCOM inspectors in Iraq to recognize questionable situations almost at first glance.

Getting publicizable proof was the difficult part, but I emphasize again, that is not the role of the protocol. Raising suspicions or resolving them is what the protocol is about. National means can then be focused on the sites or questions of concern. The protocol's regime would effectively complement national intelligence, military power and diplomacy. In a serious situation, the protocol would provide bases broader than we now have for international action.

To achieve adequate transparency, the chairman's text of the protocol requires annual declaration of the sites of greatest potential threat, plus a variety of onsite measures: first, mandatory, ran-

domly selected visits to declared facilities; second, visits to clarify any remaining questions if clarification consultations should fail; and third, mandatory challenge investigations anywhere.

It's ironic that while we suspect Iraq of continuing its biological weapons program and we decry its refusal to allow U.N. inspections, the United States is poised to turn down an international agreement that would provide three different means for probing suspicious installations. Even a refusal to allow access in violation of the protocol would provide information.

A former Deputy Director of the CIA, Doug MacEachin, has made a persuasive case for the deterrent effect of the protocol regime. In a recent article, he explains why the regime would prevent proliferators from using ostensibly legitimate facilities for illicit programs. To avoid raising suspicions, they would have to conduct bioweapons activities clandestinely, with all the attendant difficulties and risks.

International steps to strengthen the Biological Weapons Convention began in 1986 during the Reagan administration. They continued with the positive feasibility study I mentioned during the first Bush administration and then proceeded into the protocol negotiations 6 years ago. Throughout, there was vocal bipartisan support from the United States. We've led the chorus in citing the need for action. Now with the goal almost within our grasp, rejection of the protocol will send a message to potential proliferators that will tell them that there is no international will to enforce the ban on biological weapons. Americans will pay the price as the prime target.

Military and nongovernment experts agree that bioterrorists are highly unlikely to be able to launch a mass attack without state support. It would be foolhardy not to do all we can to cutoff the source by monitoring the compliance of states with the biological weapons ban. But this is not something the United States can do unilaterally.

The protocol is the available tool, and that's why our European and other allies are so angered and dismayed by the U.S. stance. Had the United States stood with its allies and presented a united front at the negotiations, the chairman's protocol text would be stronger now. Had the United States not demanded many weakening concessions, the text would be better. But one thing is clear. The protocol does not suffer from any lack of technical information. The problems are political, not technical. Although the United States submitted no reports on trial onsite activities, 12 trials have been reported by other countries, most of them U.S. allies. And some of the trials took place at facilities belonging to the very same corporations that are major players in the United States.

I have a table which may be projected here, but I believe the Members have copies, and you can't read it anyway, but you have copies. It's a 3-page table which shows the trial visits that have been carried out. I will just point out that many of the trials involved more than one country or included foreign observers, and no U.S. trial will have any credibility that doesn't do the same.

All the trials that have been carried out concluded that the visits would be effective in strengthening the convention and increasing

confidence in compliance, and that confidential information could be protected at the same time.

In addition to the trials, there are copious data from the many different national and international inspections that are carried out routinely at sites relevant to the protocol, both here and in many other countries. The chairman's text meets all the essential demands of U.S. industry. It provides more safeguards for confidential information than the Chemical Weapons Convention, which covers many of the same facilities and to which we are already a party.

As for export controls, the rhetoric of the text may please the critics of the Australian Group. The Australian Group is a cooperative mechanism for controlling dual-use chemical and biological exports. But the substance of the chairman's text is fully in line with the western position. There are only guidelines, no hard obligations regarding exports. Each state party has full discretion over every measure suggested in the text.

In closing, I'd like to point to several additional actions that need to be taken to supplement the protocol in controlling biological weapons. These are described in my written testimony, and there's no time here now. One of these actions is a program for effective global surveillance of emerging diseases. This program, proposed by an alliance of the World Health Organization and several other health groups, known as AllAID, Would fulfill the obligations of parties to the convention to "cooperate for the prevention of disease," to use the words of the convention.

To do this, the proposed program addresses the specific goals already agreed by the protocol negotiators, but there is little hope of funding this necessarily multilateral program without the incentives that the protocol would provide. And I hope in the question period we will have a greater opportunity to discuss this program. Thank you very much.

Mr. SHAYS. Thank you very much, Dr. Rosenberg.

[The prepared statement of Ms. Rosenberg follows:]

Testimony of Barbara Hatch Rosenberg, PhD

Before the Subcommittee on National Security, Veterans Affairs and International Relations, House Committee on Government Reform

Hearing on The Biological Weapons Convention Protocol: Status and Implications
June 5, 2001

My thanks to Representative Shays and the Subcommittee for giving me the opportunity to speak for the many expert non-governmental organizations and individuals in this country and elsewhere, the vast majority of whom support the rapid completion of a Protocol to strengthen the Biological Weapons Convention (BWC).

I am Dr. Barbara Hatch Rosenberg, a molecular biologist formerly of Cornell Medical College and now Research Professor at the State University of New York. I chair the Federation of American Scientists' (FAS) Working Group on Biological Weapons, a core group of ten professionals with expertise ranging from technical to medical to legal to political, and, in addition, dozens of collaborating consultants on specialized issues. All of us volunteer our efforts in the hope of contributing to the control of a looming, long-term global threat that is increasing every day along with the explosive growth of knowledge in the biological sciences and technology.

The FAS Working Group has monitored the course of the BWC and contributed to every effort to strengthen it for more than twelve years. Until quite recently we were the only NGO involved. Our institutional memory and technical expertise surpasses that of nearly all the Protocol negotiators, who come and go while we stay on with our focus fixed on biological weapons issues. Our verification credentials derive from a series of trial inspections carried out in the early '90s, numerous in-depth discussions with inspectors and inspection agencies such as FDA and UNSCOM, constant research, and a broad acquaintance with most of the actors in the field, including the negotiating teams from many countries. We have contributed nearly 50 Reports and Working Papers on technical issues to the negotiations and sponsored many seminars and workshops in Geneva for the negotiators. We have always worked closely with representatives of the pharmaceutical and biotechnology industries and have issued two joint papers with PhRMA representatives.

US Policy and the BWC Protocol

Ever since President Nixon unilaterally renounced biological weapons, there has been bipartisan support for the BWC and, under Ronald Reagan, George Bush (Sr.) and Bill Clinton, vocal US support for strengthening it. Under the previous Bush Administration, the United States participated in a verification feasibility study known as VEREX (carried out by Verification Experts from the BWC parties), which issued a positive report. A series of international steps, begun in 1986, have brought us close to the goal of a legally-binding compliance regime for the BWC.

Throughout the six years of Protocol negotiations, however, virtual deadlock in the inter-agency process prevented United States leadership and greatly limited US contributions. With each agency most interested in protecting its own turf, there has been no participant who has had both the vision and the power to insist on the public interest. It is one of the weaknesses of our government that these short-sighted bureaucrats have endured and will continue to do so regardless of the Party in power. Only high-level determination, like that of George Bush (Sr.) to complete and sign the Chemical Weapons Convention, will override these narrow interests. Informed oversight by the legislative branch could also play an important role.

Consequently, at the Protocol negotiations the ball has been carried by our allies, particularly the United Kingdom, which served as Friend of the Chair for Compliance Measures. The UK has devoted great effort to research and develop an effective compliance regime. Their proposals have been applauded by many outside experts. If the Western Group had stood solidly behind the original British contributions to the rolling text we would have a much stronger Protocol text now. But US objections forced continual weakening of the text, and the obvious split in the Western Group prevented the West from negotiating from strength with other Blocks. Countries like China have been able to use the United States as a shield for their views. Rejection of the Chairman's Text for the Protocol puts the United States in a position more extreme than that of the radical fringe--China, Libya, Cuba, Iran and Pakistan--which have expressed significant objections but not outright rejection of the text.

The Politics of the Chairman's Protocol Text

US objections to the strong Protocol measures originally advocated by our allies centered around the declaration of Biological Defense facilities. This year, new objections were added, including opposition to declaration of non-governmental production facilities. Once US objections were voiced, it became essentially impossible to reach consensus on anything stronger. The US positions embolden the likes of China or Cuba to behave similarly. Incorporation of US demands in his compromise text left the Chairman in a weakened position to deal with the demands of other countries. Our allies consider the Chairman's text to be the best that can now be achieved. At the same time, they consider it the bottom line and want no further compromises.

Moreover, the negotiators are close to the end of their patience and our allies see no point in continuing to spar unproductively with the United States. We are within reach of the goal. If consensus cannot be reached soon with minor adjustment of the Chairman's text, it means that there is no political will to strengthen the BWC.

Endangering the International Norm against Biological Weapons

Unless it can be seen by the end of the remaining four weeks of negotiation that agreement is near, there is sure to be a contentious row at the fifth BWC Review Conference in November, with quite likely a lack of agreement on what to do next. The United States is certain to receive most of the blame. We led the chorus in citing the

danger; if we turn down an international step toward prevention that is almost within our grasp, it will tell potential proliferators that the international community is not prepared to enforce the ban on biological weapons. As citizens of the lone superpower, Americans would be a prime target if these weapons were used either strategically or as an instrument of terror. Even without use, the proliferation of biological weapons entails a serious risk of escape and the possible establishment of new and uncontrollable diseases in the biosphere. There are no military weapons that can "take out" an emerging disease.

Bioterrorism Requires State Sponsorship

US military experts, and studies by many non-governmental experts, agree that, at present and for some time to come, terrorist groups are highly unlikely to have sufficient expertise and resources to succeed in a mass attack with biological weapons. Aum Shinrikyo, the Japanese terrorist group, had plenty of both but failed in nine attempts to mount a biological attack. Although the United States has so far concentrated on preparations for mopping up after a bioterrorist disaster, it would be foolhardy to ignore the more important goal of cutting off the source by preventing the proliferation of biological weapons. That is not something the United States can do unilaterally. The first step must be international, and strengthening the BWC is the available tool. That is why our European and other allies are so angered and dismayed by the US stance.

What the Protocol Could Do

A verification regime that can be relied upon to detect violations of the BWC is impossible. That is not what the Protocol is about, and not what the negotiators have ever tried to do. Too much of what is needed to develop biological weapons also has peaceful uses. In such "dual-use" situations, the objective is **transparency** with regard to relevant capabilities.[1] This was an intrinsic premise in the VEREX feasibility study and its positive outcome.

Sufficient transparency can be achieved by requiring declaration of relevant installations and providing means for clarifying any questions that may arise regarding the declarations, including whether or not relevant sites have NOT been declared. The Chairman's text does this. It requires declaration of the sites of greatest potential threat, and it provides several different means for getting on site (which, if blocked by the party in question, would also yield information).

The intrinsic tension between transparency and confidentiality means that, in *any* biological weapons regime, no smoking guns are likely to be found. Although inspectors' on-site activities have to be subject to limits in order to protect confidential information, that doesn't mean that nothing will be learned. In Iraq, UNSCOM inspectors met with great difficulties in obtaining hard proof, but they were adept at

[1] Novices often assume that "transparency" means divulging exactly what is going on in a facility. That is not the case. It is the facility's *capabilities* that must be revealed. Experienced inspectors can then judge whether those capabilities make sense for peaceful purposes and are consistent with the alleged purpose of the facility.

spotting inconsistencies with the stated purpose of a site and they quickly recognized what questions needed to be answered. Raising suspicions, or resolving them, is what the Protocol is about. National means can then be focused on the sites or questions of concern. The Protocol's compliance regime would effectively complement national intelligence, military power and diplomacy. In serious situations the Protocol would provide a basis, broader than we now have, for international action.

The Chairman's text provides a variety of on-site measures:

- mandatory randomly-selected visits to declared facilities;
- visits to clarify remaining questions when consultations fail (these may be voluntary or can be pursued through the Executive Council to become mandatory);
- mandatory challenge investigations anywhere, including both facility and field investigations.

Douglas MacEachin, former Deputy Director of the CIA, has made a persuasive case for the **deterrent effect** of non-challenge visits. In a recent article he points out that, ideally, a proliferator would use a commercial plant as a cover for a biological weapons program, thereby facilitating operations and the procurement of dual-use equipment and materials. But if the plant had to be declared, he would not take the chance that inspectors might obtain enough information during a visit to raise new suspicions. Instead, the illicit activity would be forced into undeclared, clandestine operation, with all the attendant risks. Any evidence of suspicious activity at an undeclared site could lead to intense surveillance, a clarification process under the Protocol or a challenge investigation.

The Chairman's Protocol text calls for a 50% vote of Executive Council members present and voting to authorize a challenge investigation at a suspected facility. An FAS study recommended this formula as the best means for preventing ill-founded investigations without unduly inhibiting the use of this important measure or impeding its **deterrent** effect. Although challenge investigations have political costs and will not be used often, it is likely that, had the Protocol been in existence, the political situations would have permitted the invocation of challenge investigations in past cases where allegations eventually proved to be true, such as the anthrax outbreak at Sverdlovsk in 1979. A challenge at that time would have forced the Soviet Union to flout the terms of the treaty and refuse access. That might have had a dampening effect on their subsequent biological weapons build-up.

It is ironic that, while suspecting Iraq of continuing its biological weapons program and decrying its refusal to allow UN inspections, the United States is poised to turn down a treaty that would provide a variety of means for probing suspicious installations by going on site.

The US Critique of the Protocol

The US policy review has rejected the Chairman's text on the grounds that

a) it is too weak,

b) it would threaten national security and commercial proprietary information, and

c) it threatens the Australia Group and its "dual use" export control regime.

a) Weakness:
With regard to weakness of the text, the old argument of not being able to detect violations (meaning *always*, and with *certainty*) is frequently invoked. As discussed already, this is not and could not possibly be the purpose of the Protocol. If this were the only criterion of interest to the United States, we should never have participated in the negotiations in the first place.

Furthermore, the US delegation has made it known in Geneva that they will not support *any* Protocol based on the present negotiation mandate, but would prefer a much more limited mandate—which would inevitably lead to a more limited Protocol. A more limited Protocol--say, containing only challenge investigations--would be weaker, not stronger.

Finally, the weaknesses in the text are largely there in compliance with past US demands, including the following:
--The text does not require declaration of all biodefense facilities; only those conducting certain activities, and only those above a certain size. There are ample loopholes to satisfy DoD specifications.
--The text requires no significant information about production facilities for pharmaceuticals (other than licensed vaccines), and exempts them from visits! No problem there for American pharmaceutical companies.
--All on-site activities of inspectors during visits are at the discretion of the host government, and all procedures during challenge investigations are subject to managed access.
--All visits require at least two weeks notice.

FAS has advocated stronger measures than these, but we recognize the necessity for compromise and the role played by the United States in shaping those compromises. Any American who criticizes the Chairman's text for being too weak has to be either disingenuous or ignorant of the political situation.

b) Confidentiality:
The Chairman's text possesses more safeguards for confidential information than the Chemical Weapons Convention of 1993 (CWC), to which we are already a party and which covers most of the same facilities: those handling toxins (including the US biodefense program), for example, fall under both treaties; most pharmaceuticals are manufactured chemically, and therefore are "discrete organic chemicals" covered by the CWC. And challenge inspections under the CWC can take place "anytime, anywhere," as President George Bush (senior) insisted.

Unlike the CWC, for example, the Protocol text allows no sampling and analysis in non-challenge visits, and gives control of access to the host country. These aspects of the Protocol text comply with the wishes of US bioindustry, which is particularly concerned about protecting its proprietary microbial strains. There are, in addition, all the

protections for confidentiality that were developed for the CWC with the help of the chemical industry. The exemption of certain defense facilities and of most pharmaceutical facilities from declaration under the Protocol, discussed above, provides additional protections for confidential information.

The Chairman's text more than meets all the essential confidentiality concerns of the pharmaceutical and biotech industries. Further safeguards for industry could be incorporated into US Protocol implementing legislation, and, when the time comes, we and our industry colleagues will be happy to work with the members of this Subcommittee to help develop appropriate implementation measures.

c) Export Controls
One only need read Article 7 of the Chairman's text to realize that its rhetoric is meant to please the critics of the Australia Group but its substance tilts heavily toward the West. The text contains only guidelines,with *no* hard obligations regarding exports; each State Party has full discretion over implementation of the suggestions in the text.

On-site Trials as a Basis for the Protocol

One thing is certain: any weaknesses in the Protocol do not stem from inadequate technical information. Although the United States has submitted no reports on trial visits or investigations to the Protocol negotiations, twelve trial visits have been reported by other countries, most of them US allies (See appended table). Half of these trials involve more than one country, or included foreign observers. All of them concluded that non-challenge visits would be effective in strengthening the BWC and increasing confidence in compliance. They also concluded that confidential information could be protected at the same time. Americans should be aware that protection of their defense establishments and bio-industry is of great importance to our allies, as it is to us. In formulating their policies our allies have worked productively with *the same* multinational corporations that are the major players in the United States.

In addition, copious amounts of information were available from trial inspections conducted by the United States and many other countries not so long ago during negotiation of the CWC, from the UNSCOM experience in Iraq, and from the experience of multiple types of national and international inspections carried out routinely at sites relevant to the Protocol by many countries.

It would be desirable for the United States to carry out on-site trials of its own in order to allay the fears of those potentially affected, but to be credible at this stage, such trials would have to be multilateral and would have to make a special effort to demonstrate the absence of bias.

Additional Mechanisms for Controlling Biological Weapons

1. *Global Surveillance and Control of Emerging Diseases*

Article X of the BWC requires scientific/technological cooperation for the prevention of sease and other peaceful purposes. The negotiators of the Protocol recognize that this promise must be implemented in a specific way in the Protocol. A set of goals has been fully agreed by the negotiators and is contained in the Chairman's text; most of these concern surveillance, detection, diagnosis, and control of infectious diseases. The World Health Organization and several other health organizations have formed an Alliance Against Infectious Diseases (AllAID) that has proposed a specific mechanism for accomplishing the cooperative aims of the Protocol. The proposed program, to be funded by Protocol parties, would establish a network of about ten regional epidemiological/diagnostic Centers, strategically located in the developing world. Each Center would establish its own regional network and provide training in outbreak recognition and control. Advanced training and research on regional disease problems would also be supported. The program has a two-fold aim: regional self-sufficiency in handling infectious diseases, and global early warning of emerging diseases. This program would serve as an important incentive for adherence to the Protocol, while at the same time providing a means for speeding the recognition and control of any use or escape of biological weapons. When the program is in full force it will have the effect of deterring the use or testing of biological weapons by strengthening the capacity of all regions, especially those that are now the weakest, to recognize or diagnose unusual outbreaks.

2. Ethical Education of Biological Scientists

Few bioscientists anywhere now emerge from their formal academic training with an derstanding of the dilemmas their future work may pose. Subsequent immersion in eir professional specialties often leads to a bias against considering any potential negative aspects, lest research be restricted in some way. There is little or no awareness of international concerns and prohibitions on the misuse of biology. The development of appropriate courses and educational materials that could be widely used is desperately needed.

The Federation of American Scientists has initiated a collaborative project to develop a collection of cutting-edge web-based materials that could stand alone as a course or be incorporated in existing courses at universities around the world. The project, entitled "The Biological Sciences: Risks, Responses and Responsibilities," will involve contributors from many countries.

3. International Self-Monitoring of Bioscience

A number of organizations are now studying possible non-governmental means for ensuring transparency and establishing some form of oversight on work with pathogens and other biologically-active materials. It is too early to discuss or predict the outcome of these efforts.

Trial Visits

Official Reports to the Ad Hoc Group

* Working Paper concludes visit is potentially useful
# Working Paper concludes confidential information can be protected

Session	Working Paper	Submitted by	Type of Facility	Inspectors and Observers
Session 21 Working Papers (BWC/AD HOC GROUP 54)	Practice randomly-selected transparency visit to a biodefence facility WP.437 13 December 2000 * #	Australia	Biodefence Facility	Australian team
Session 19 Working Papers (BWC/AD HOC GROUP 51)	Report on a trial transparency visit to a biological defensive facility WP.414 17 March 2000 * #	Spain	Biodefence Facility	Spanish team (Ministries of Foreign Affairs, Health Education and Defence)
Session 16 Working Papers (BWC/AD HOC GROUP 47)	Report on two trial visits based on a transparency visit concept WP.398 24 August 1999 * #	Germany	Industrial Production Facility	German team and a visiting team consisting of three people from three other States Parties
Session 15 Working Papers (BWC/AD HOC GROUP 46)	Report on a Trial Inspection (Random visit) WP.371 10 June 1999 * #	Switzerland	Industrial Production Facility	Swiss team and a representative of the Ministry of Defence in Austria
Session 13 Working Papers	Report of a National Trial Visit to a Vaccine and Serum	Islamic Republic of Iran	Vaccine and Serum Production Facility	Iranian team

(BWC/AD HOC GROUP 44)	Production Facility WP.345 14 January 1999 * ≠			
Session 12 Working Papers (BWC/AD HOC GROUP 43)	Report on an international trial random visit WP.310 23 September 1998 * ≠	Austria	Pharmaceutical Facility	Austrian team and visiting team consisting of four representatives from Japan, Germany and Switzerland
Session 12 Working Papers (BWC/AD HOC GROUP 43)	Report of a trial random visit to a biopharmaceutical production facility WP.298 21 August 1998 * ≠	Denmark, Finland, Iceland, Norway and Sweden	Biopharmaceutical Production Facility	Home team (government representatives, technical experts and representatives of the facility) and a visiting team consisting of five persons from three other countries
Session 9 Working Papers (BWC/AD HOC GROUP 39)	Report of a visit to a Pharmaceutical Research Facility WP.258 09 January 1998 * ≠	United Kingdom	Pharmaceutical Research Facility	Home team
Session 9 Working Papers (BWC/AD HOC GROUP 39)	Use of a simulated declaration format in a practice visit WP.251 17 December 1997 *	United Kingdom	Industrial Facility	Home team
Session 4 Working Papers (BWC/AD HOC GROUP 31)	Trial inspection of a biological production facility WP.77 18 July 1996 * ≠	Australia	Biological Production Facility	Australian inspection team

Session 4 Working Papers (BWC/AD HOC GROUP 31)	Report of a joint UK Brazil practice non-challenge visit WP.76 18 July 1996 * =	Brazil and the United Kingdom	Vaccine and Serum Production Facility	Brazilian and UK teams and an additional representative of PAHO (Pan American Health Organization)

ROUTINE AND CHALLENGE: TWO PILLARS OF VERIFICATION

Douglas J MacEachin
Deputy Director for Intelligence
US Central Intelligence Agency 1993-1995

The Geneva negotiations on a protocol for verifying compliance with the 1972 Biological Weapons Convention (BWC) have so far been unable to produce agreed provisions for visits of inspectors to declared facilities that are especially suited for possible weapons purposes. A significant factor in this lack of agreement has been the qualified United States support for such visits. Although many U.S. officials have indicated support for the visits, according to Marie Chevrier (Washington Post, 21 December 1997) some worry that a strong inspection protocol could create misguided confidence in the compliance of other signatories, thereby undermining budgetary support for military defenses. Others are concerned over potential exposure of proprietary information from biological facilities engaged in defense and commercial undertakings.

These issues are not new or unique to the BWC. The "misguided confidence" argument has been part of the debate on every arms control treaty as far back as SALT I. The burden of protecting sensitive information, whether in national security facilities or commercial enterprises, is inherent to the on-site inspection process.

Moreover, the magnitude of the protection burden is directly proportional to the difficulty of distinguishing treaty violations from legitimate activities. The more that there are materials, equipment, human resources and other elements that are common to both legitimate and prohibited activities, the easier it is for a treaty violation to be hidden under the cover of legitimate activities. That is precisely what makes violations of the BWC so difficult to detect. Absent a regime for subjecting legitimate activities to a high degree of transparency, the best way for a violator to carry out a covert program would be to bury it -- piggy-back it -- inside a legitimate program. (As the former Soviet authorities sought to do under their Biopreparat cover.)

Consequently, the more there are common elements between proscribed and legitimate programs, the more critical is the need for transparency of the legitimate activities. The greater the need for such transparency, however, the greater the challenge to protection of proprietary information. This issue has been confronted in all of the on-site inspection regimes for existing treaties. The most difficult problems were encountered in the visits required under the Chemical Weapons Convention, where the level of ambiguity between legitimate and proscribed activities is similar in nature to the BWC.

Up to now, the risks to proprietary information have not been judged by US decision makers as sufficient to warrant forgoing the security benefits of incorporating robust verification measures in arms control treaties. Hopefully, the debates on provisions for a strengthened verification protocol for the BWC -- whatever the conclusions that result from those debates -- will be based on assessments of the benefits and risks to national security rather than parochial concerns.

If this is to occur, however, the strengths and weaknesses of on-site visits have to be addressed in the context of their role in the overall verification architecture.

By employing a "legitimate activity" cover, a treaty violator can avoid the need to conceal

the various materials, equipment and activities associated with a proscribed weapons program -- they can be sequestered within a legitimate activity. Only the purposes of these elements need be concealed. If the violator can be deprived of the legitimate cover, however, he must conceal the existence of all activities involved in the proscribed weapons effort.

Therefore, the defining objective of on-site verification architecture in the major arms control treaties -- whether bilateral agreements limiting nuclear delivery means or multilateral treaties limiting conventional weapons in Europe or eliminating chemical weapons globally -- has been to deny a potential treaty violator the means for concealing proscribed programs under the cover of legitimate activities. This architecture applied to the BWC would consist of the following requirements:

(1) Each party would be required to submit a "declaration", identifying by location and description all sites and facilities where there are specified characteristics, such as certain biological agents and equipment and/or activities related to the acquisition, transport and processing of biological materials for legitimate purposes but which could also be especially relevant to possible weapons purposes. A specific intent of this declaration is to establish that the presence of any such specified characteristics, whatever their purpose, at a site that is not declared might represent non-compliance with the basic prohibitions of the treaty.

(2) Each declared site would be subject to "auditing" visits with no treaty right of refusal. There would of course be limitations such as numerical quotas and rules for conduct designed, *inter alia*, to prevent abuse, but the critical principal should be to make the declared sites "unsafe" for use as cover for proscribed activities. In the current terminology of the Geneva negotiations, such visits would presumably include what are designated as "random" and "clarification" visits, both of which are included in the general category of "non-challenge" visits. In other arms control regimes, non-refusable visits to declared facilities are known as "routine" visits.

(3) Sites that are not declared would be subject to "challenge" visits to resolve issues arising from evidence of the presence of activities that could be part of biological weapons programs.

The critical element that binds the on-site verification architecture together is that there is no treaty right of refusal for visits to declared sites and that those visits will be carried out in accordance with agreed procedures to meet an agreed minimum level of transparency.

Visits to declared sites are in direct contrast to challenge visits, which are intended for sites not defined in advance. Since any site is technically liable to challenge, such visits must be authorized and conducted under procedures designed to constrain them from being exploited for information gathering outside the bounds of the treaty. These procedures would include requirements for presentation of causal justification for conducting the visit, approval by some treaty-empowered body for adjudicating the case for the challenge, constraints on the amount of transparency that can be imposed, and an ultimate right of refusal by the challenged party.

In combination, these mutually supporting visitation provisions seek to create a synergistic force that presents only bad choices to a state wishing to produce biological weapons:

(1) Carrying out the weapons program at a declared site -- a site that is subject to visits that cannot within the provisions of the treaty be refused. This requires ensuring that all signs of the program be concealed from the visiting team. Some opponents of a rigorous regime for non-challenge visits argue that the nature of biological weapons programs is such that this concealment is easily done. Maybe. But how much confidence is the violator to have that this

can be done? To what extent is the violator prepared to stake a weapons program on this gamble? How does the violator know what kind of information might have been in the hands of the visiting team before it undertook the visit? One argument has been that it takes only a short time after the departure of a visiting team to convert a legitimate biological research facility to production of biological weapons. [Alan Zelikoff, Washington Post, 8 January 1998]. This is puzzling since it bypasses the issue of covering up all indications that a program was underway before the visiting team arrived. If the cover-up takes place at a facility at which there are otherwise legitimate biological programs, are all of the personnel working on the legitimate activities privy to the conspiracy? If not, isn't there a risk that the cover-up in anticipation of a non-challenge visit could be detected by citizens who might leak the information further? Indeed, experience has shown that often it is the cover-up efforts that expose the illicit activity, rather than the illicit activity itself. All things considered, these are risks that a regime seeking biological weapons probably would wish to avoid if possible. One way of avoiding them is to ensure that there is no regime for non-challenge visits to declared sites, or to ensure that the "rules of engagement" for such visits render them merely symbolic.

(2) Another way to avoid these risks would be to attempt to carry out the weapons program at a site that is not declared and is therefor not subject to random or other "auditing" visits. This, however, would require perfect secrecy -- a "leak-proof" operation. Being perfectly leak-proof means all signs of acquisition, transport, storage, processing, and the related communications, safety, security and personnel actions must be totally concealed. Again, that may be technically possible, but history has demonstrated that total secrecy is seldom if ever maintained indefinitely. The more complicated the activity the more likely that some indications will be exposed, especially when concerted efforts, including advanced technologies, are devoted to discovering them. Any snippets of information indicating, for example, the acquisition or presence of certain biological materials and/or equipment, or employment of biological technicians at an undeclared site, however ambiguous the information, could result in the site being subjected to a challenge investigation. Refusal privilege could ultimately be invoked to block the investigation, but not without causing the activity to be a publicized focus of scrutiny. The more evidence presented to support the challenge the greater is the political burden of refusal, as the challenged site becomes a permanent entry on the "suspect target" list. Given the choices, most producers of weapons of mass destruction prefer to avoid the challenge of "perfect secrecy" by burying the activities under the cloak of an ostensibly legitimate activity, so long as the claim of legitimate activity is not itself at risk of being shown to be false by a "non-challenge" visit.

(3) The third option would be to simply avoid both sets of problems by refusing to become a party to the treaty protocol. That carries its own burden, and helps remove some of the ambiguity for planning countermeasures and designing military target options. The rogues have declared themselves.

It is important to note that the effect of these on-site verification regimes comes from their complementary nature. The utility of one type of regime is severely reduced -- arguably marginalized -- if it is not complemented by the other.

Within this architecture the effectiveness of visits to declared sites does not have to be measured against the likelihood that such visits would "catch" a treaty-prohibited weapons program. Such "catches" have occasionally been made in the routine inspections carried out in other treaties, and they always remains a possibility. Nonetheless, the instances when this has

occurred have resulted mainly from slip-ups by the treaty violator -- reflecting carelessness, incompetence, hubris, or all three -- in allowing the activity to take place under the risk of exposure from the visits. As a practical objective the most important contribution of non-refusable visits to declared facilities is to impede a potential violator's ability to mask signs of a prohibited weapons program behind the cover of legitimate activities.

To achieve this effect, however, visits to declared sites must be complemented by the possibility of challenge visits. Otherwise, a weapons program can be shielded from the risk of exposure to visits simply by carrying it out at undeclared sites. While the violator would still attempt to keep all signs of prohibited biological activity totally secret, the costs of failing to meet this requirement would be reduced by the absence of the threat of a challenge visit. With no treaty provision for challenge, the violator could simply fall back as a last resort on a public denial stonewall, without the burden of having to refuse a challenge visit.

Conversely, the constraints that must be imposed on challenge visits to prevent them from being exploited for critical security and commercial information undercuts their potential for exposing -- by themselves -- a proscribed program. But complemented by a no-refusal visit regime for declared sites, the effectiveness measure for a challenge visit to an undeclared site does not have to depend solely on its likelihood of proving the existence of a weapons program. It only has to demonstrate, through evidence, that the challenged site meets the requirements for being on the declared list. In that case, the challenged party has been shown to be in non-compliance with the treaty. Compliance could be restored by making an appropriate declaration, placing the site in the "declared" category and thereby automatically subjecting it to non-refusable "auditing" visits from then on. Of course, there is the further possibility that the challenge visit will produce other information relevant to the concerns that gave rise to the challenge.

There have been suggestions (e.g. Zelikoff) that challenge investigations by themselves are the only kind of visits that are needed. Given the potential for abuse of challenge investigations, however, how are they going to be designed to achieve the ability to ferret an illegal program from the noise level of a legitimate program without sacrificing the necessary protection of proprietary information? How will the evidential threshold for justifying a challenge investigation be defined for a site already declared to be engaged in legitimate biological activity? Such evidence cannot rest on discovery of the presence of materials and activities arguably engaged in permitted biological activities, since that is what the facilities are declared to be doing.

In the end, all of these considerations have to be balanced against costs and risks. Such cost -- risk assessments would be fundamentally flawed, however, if they attempted to evaluate the impact of non-challenge visits and challenge visits separately, rather than as the two halves of an integral structure. This is an architecture within which the weakening or elimination of one pillar has a major impact on the remaining pillar.

from *The Chemical Weapons Conventions Bulletin*
Issue No. 39, March 1998, pp 1-3.

Mr. SHAYS. Dr. Woollett.

Ms. WOOLLETT. Good afternoon. My name is Dr. Gillian Woollett. I'm the associate vice president for biologics and biotechnology at PhRMA, the trade association for research-based pharmaceutical and biotechnology industries in the United States. We are pleased to have the opportunity to share with this subcommittee our industry's views on the development of a protocol to the Biological Weapons Convention. PhRMA appreciates the very complicated challenge that the signatories to the BWC face in trying to assemble a protocol that provides any level of confidence for either compliance or verification of the BWC. We welcome the opportunity to work with the subcommittee——

Mr. SHAYS. Doctor, you can just move yours. I rarely have the occasion to ask someone to move it away. Just step it 2 inches away.

Ms. WOOLLETT. We welcome the opportunity to work with the subcommittee as you explore and deliberate these very important issues. PhRMA concurs with the goals and objectives of the BWC and has been actively supporting efforts to strengthen this convention by the inclusion of effective measures to help enhanced compliance with its objectives and to reduce the threat of biological warfare.

Indeed, the global pharmaceutical, chemical and biotechnological industries join others in their belief that biological weapons represent a serious and increasing danger to people around the world. Since very similar microorganisms to those used for legitimate purposes could be misused as weapons of mass destruction, we accept that a protocol strengthening the BWC cannot exempt private industry.

However, the pharmaceutical and biotechnology industry does not make biological weapons. Our very purpose is the opposite. We make products to counter unmet medical need, of which a substantial proportion continues to be infectious disease. To compromise our ability to develop medicines or to undermine patients' confidence in those medicines without a definable level of confidence in the proposed protocol would be a tragedy for public health.

The chairman's text unduly targets vaccines and culminates in requirements that not only compromise our industry's ability to research and manufacture medicines but also establishes mechanisms to expose confidential business information.

Measures strengthening the BWC should ensure the inhibition of any misuse of microbiology without impairing its legitimate lifesaving uses. We should encourage development in areas such as health care, agriculture, nutrition and the environment. Our concerns with the protocol include the scope of declarations and onsite activities and the degree to which the burden is balanced by its value for arms control purposes.

Declaration formats must be simple and without requirement for disclosure of any confidential business information, and their use must be apparent in impeding biological weapons creation. Unfortunately, these criteria are not met in the current chairman's text. The current triggers in the chairman's text are ambiguous and the focus is on those facilities with greatest legitimate capabilities.

Furthermore, the declarations are extensive. The format is confusing, and they will require inclusion of confidential business information.

PhRMA urges that clarification procedures between the International Secretariat and the state party be established in anticipation of questions about declarations. However, we believe these procedures should not require any additional onsite activities.

Since the nature of microbiology is such that it is often easy to remove traces of any development, manufacture, or storage of a biological weapons agent, any routine onsite activity is not a useful concept under the protocol. However, our industries are sympathetic to the concept of nonroutine, nonrandom familiarization or educational visits, provided they are voluntary and under full control of the company visited.

In the event of alleged serious violations, it may be appropriate for the international community to conduct a challenge inspection, but malicious or frivolous claims of violations must not precipitate intrusive onsite activities. Challenge inspections must be conducted according to an established due process that is evidence based. Strict managed access must be employed, and the inspected site must have the final determination of what is proprietary information. If no evidence of a violation is found, this fact must ultimately be reported by the International Secretariat.

The global pharmaceutical, biotechnology and chemical industries have tried to participate actively to reduce the threat of biological weapons. Working globally with our respective governments and international negotiators, our companies believe that our industry can help strengthen the BWC and reduce the serious threat to people around the world. Unfortunately, the chairman's text, as proposed, strongly suggests that our input to date has fallen on deaf ears.

As you deliberate this difficult topic, we urge that you include the needs of patients and their intimate relationship and confidence in our companies in the equation. More and better medicines are dependent on the ongoing research and manufacturing capabilities of the U.S. pharmaceutical and biotechnology industries. A global leadership is a credit to the United States and not something to be intruded upon in the search for biological weapons, which are clearly an anathema to our industry. One of our industry's greatest contributions to public health has been human vaccines, and yet vaccines find themselves in the bull's-eye of this protocol. How can that help global security? Thank you.

Mr. SHAYS. Thank you, Dr. Woollett.

[The prepared statement of Ms. Woollett follows:]

Statement PhRMA

GILLIAN WOOLLETT, Ph.D.
ASSOCIATE VICE PRESIDENT
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS' AFFAIRS
AND INTERNATIONAL RELATIONS

U.S. HOUSE OF REPRESENTATIVES

JUNE 5, 2001

Good morning. My name is Dr. Gillian Woollett and I am the Associate Vice President for Biologics and Biotechnology at the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association for the research-based pharmaceutical and biotechnology companies that are devoted to inventing new life-saving, cost-effective medicines in the United States. We are pleased to have the opportunity to share with this Subcommittee our industry's views on the development of the "compliance" or "verification" protocol to the Biological Weapons Convention (BWC).

PhRMA supports the goals and objectives of the BWC, in effect since 1975, and has been actively supporting efforts to strengthen this Convention by the inclusion of effective measures to help enhance compliance with its objectives and to reduce the threat of biological warfare. Indeed, the global pharmaceutical and biotechnological industry joins others in the belief that biological weapons represent a serious and increasing danger to people around the world. That is why PhRMA has been active since first speaking publicly at the 1996 BWC Review Conference and has joined our sister industries globally to advocate a common position with a joint statement (copy attached).

PhRMA appreciates the very complicated challenge that the signatories to the BWC faced in trying to assemble a protocol that provides any level of confidence, for either compliance or verification, of the Biological Weapons Convention. We welcome the opportunity to work with the Subcommittee as you explore and deliberate these very important issues.

Micro-organisms are being used every day in homes, educational establishments and by private industry to benefit society - for instance, to make bread, cheese and beer, to promote animal health, as well as to create critically important and life-saving medicines. Since very similar micro-organisms to those used for such legitimate purposes could be misused as weapons of mass destruction, we accept that a protocol strengthening the BWC cannot exempt private industry.

However, the pharmaceutical and biotechnology industry does not make biological weapons – our very purpose is the opposite: we make products to counter unmet medical need, of which a substantial proportion continues to be infectious disease. To compromise our ability to develop medicines or undermine patients' confidence in those medicines, without a definable level of confidence in the proposed protocol, would be a tragedy for public health – both in this country and elsewhere amongst the signatory nations. The Ad Hoc Group Chairman's draft text, or protocol – the reason for today's hearing – unduly targets vaccines and culminates in requirements that not only compromise our industry's ability to research and manufacture but also establishes mechanisms to expose confidential business information.

Since our companies are only engaged in the legitimate use of microbiology and the newly emerging biotechnologies, compliance measures affecting their activities and facilities need to be addressed carefully. Measures strengthening the BWC should ensure the inhibition of any misuse of microbiology and newly emerging biotechnologies for weapons of mass destruction, without impairing their legitimate life-saving uses and continuing development in areas such as health care, agriculture, nutrition and the environment. Our concerns with the protocol include the scope of declarations and on-site activities and the degree to which the burden of the protocol on legitimate activities is balanced by its value for arms control purposes – a balance that has not been successfully achieved in the draft Ad Hoc Group Chairman's text.

Our industry supports simple declarations of relevant activities, in order to promote transparency and build confidence that their facilities engage in legitimate enterprises. However, triggers for declarations under the protocol must be precisely analyzed and defined so as to encompass only those private industry facilities of greatest relevance to the detection and deterrence of biological weapons. Declaration formats must be simple and without a requirement for disclosure of any confidential business information. The information's use must be apparent in impeding biological weapons creation. Unfortunately, these caveats are not met in the current Ad Hoc Group Chairman's text. The current triggers in the Chairman's text are ambiguous, and the focus is on those facilities with greatest legitimate capabilities. Furthermore, the

declarations are extensive, the formats confusing, and they require inclusion of confidential business information.

The protocol's focus on vaccine manufacturers reflects a World War II mind set -- a time in which one had to have the pathogen on-site in order to make a vaccine. The emphasis on capability also unduly targets the U.S. – the undisputed world leader in pharmaceuticals and biotechnology. PhRMA's input on the triggers and declaration formats was not utilized. Also, no input on the protocol was sought from those U.S. agencies most expert in our industries, such as the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), during the previous Administration. PhRMA urges that clarification procedures between the International Secretariat and the State Party be established in anticipation of questions about declarations. However, we believe these procedures should not require any additional on-site activities.

Since the nature of microbiology is such that it is often easy to remove traces of any development, manufacture or storage of a biological-warfare agent, any routine on-site activity is not a useful concept under the protocol. However, our industries are sympathetic to the concept of non-routine, non-random "familiarization" or "educational" visits, provided they are voluntary and under the full control of the company visited.

In the event of alleged serious violations, it may be appropriate for the international community to conduct a challenge inspection, but improper or unsubstantiated claims of violations must be prevented. Challenge inspections in cases of suspected non-compliance must be conducted according to an established due process that is evidence-based and permits inspections. However, this process must curtail frivolous allegations. Challenge inspections must also strike the proper balance between the need to clarify a substantial claim of non-compliance while guarding the legitimate rights of private industry to protect its confidential business information. Therefore, strict managed access must be employed and the inspected site must have the final determination of what is proprietary information. If no evidence of a violation is found, this fact must ultimately be reported by the International Secretariat.

The global pharmaceutical, biotechnology and chemical industries have tried to participate actively to reduce the threat of biological warfare. We have offered our expert assistance to help speed the development of a compliance protocol to the BWC that is technically feasible and scientifically sound; one that will fully protect the legitimate rights and confidential business information of our companies, and which enables them to continue to lead the world in discovering and developing solutions in areas beneficial to society. Working globally with our respective governments and international negotiators, our companies believe that our industry can help strengthen the BWC and reduce this serious threat to

people around the world. Unfortunately, the Ad Hoc Group Chairman's text as proposed strongly suggests that our input to date has fallen on deaf ears.

As you deliberate this difficult topic we urge that you include the needs of patients and their intimate relationship and confidence in our companies in the equation. More and better medicines are dependent on the on-going research and manufacturing capabilities of the U.S. pharmaceutical and biotechnology industry. Our global leadership is a credit to the U.S. and not something to be intruded upon in the search for biological weapons – which are, clearly, an anathema to our industry. One of our industry's greatest contributions to public health has been human vaccines. Under this protocol, vaccines find themselves the bull's eye of this protocol. How can that help global security?

Compliance Protocol to the Biological Weapons Convention

A Joint Position of European, United States and Japanese Industry [1]

The Global pharmaceutical, chemical and biotechnological Industry joins others who are concerned that biological weapons represent a serious and increasing danger to people around the world. We support the goals and objectives of the Biological Weapons Convention (BWC), in effect since 1975, and are actively supporting efforts to strengthen this Convention by the inclusion of effective measures to help enhance compliance with its objectives and to reduce the threat of biological warfare.

Micro-organisms are being used every day in homes, educational establishments and by private industry to benefit society - for instance, to make bread, cheese and beer, promote animal health, as well as to create critically important and life-saving medicines. Since very simular micro-organisms to those used for such legitimate purposes could be misused as weapons of mass destruction, we accept that a Compliance Protocol strengthening the BWC cannot exempt private industry.

However, since our member companies are only engaged in the legitimate use of microbiology and the newly emerging biotechnologies, compliance measures affecting their activities and facilities will need to be addressed carefully when drafted. We seek to ensure that an appropriate balance is achieved between the objectives of the Compliance Protocol and the legitimate rights of private industry facilities, including the protection of intellectual property and confidential business information. Measures strengthening the BWC should ensure that any misuse of microbiology and newly emerging biotechnologies for weapons of mass destruction is inhibited, without impairing their legitimate use and continuing development in areas such as health care, agriculture, nutrition and the environment.

Our concerns with the Compliance Protocol include the scope of declarations and on-site activities and the degree to which the burden of the Protocol on legitimate activities is balanced by its value for arms control purposes.

Declarations

Our industries support simple declarations of relevant activities, in order to promote transparency and build confidence that their facilities engage in legitimate enterprises.

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[1] **Forum for European Bioindustry Coordination** (FEBC comprising AMEEP (food and feed enzymes), CEFIC (chemicals), CIAA (food), COMASSO (plant breeders), EDMA (diagnostic products), ECPA (plant protection), EFPIA (pharmaceuticals), FAIP (Farm Animal Industrial Platform), FEDESA (animal health), FEFAC (compound feed), FEFANA (feedstuffs additives) and EuropaBio (European Bio-Industries); **Animal Health Institute** (AHI, USA); **Association of Veterinary Biologics Companies** (AVBC, USA); **Biotechnology Industry Organization** (BIO, USA); **Pharmaceutical Research and Manufacturers of America** (PhRMA); **Japan Bioindustry Association** (JBA)

However, triggers for declarations under the Protocol must be precisely analyzed and defined as to encompass only those private industry facilities of greatest relevance to the detection and deterrence of biological weapons. In order to avoid a disproportionate burden on industry, declaration formats must be simple and not require any confidential business information.

In the event of questions and / or ambiguities about declarations, clarification procedures between the International Secretariat and the State Party concerned are regarded as appropriate but should not necessitate any on-site activities.

On-Site Activities

Since the nature of microbiology is such that is often easy to remove traces of any development, manufacture or storage of a biological-warfare agent, any routine on-site activity is not a useful concept under the Protocol.

However, Our industries support the concept of non-routine, non-random "familiarisation" visits, provided they are voluntary and under the full control of the company visited.

Whilst we do accept that where serious violations are alleged it may be appropriate for the international community to conduct a challenge inspection, improper or unsubstantiated claims of violations must be prevented. Challenge inspections in case of suspected non-compliance must be conducted according to a due process that is based on evidence, permits inspections and at the same time curtails frivolous allegations. Moreover, challenge inspections must strike the proper balance between the need to clarify a substantial claim of non-compliance on the one hand and the legitimate rights of private industry to protect its confidential business information. Therefore, strict managed access must be employed and the inspected site must have the final determination of what is confidential or proprietary information. If no evidence of a violation is found, this must ultimately be reported by the oversight authority.

Conclusion

Industry is an active participant in working to reduce the threat of biological warfare. We offer our expert assistance to help speed the development of a Compliance Protocol to the BWC that is technically feasible and scientifically sound and that will fully protect the legitimate rights and confidential business information of our companies, and which enables them to lead the world in discovering and developing solutions in areas beneficial to society.

Working co-operatively with our respective governments and international negotiators, we believe that our industry can help strengthenthe BWC and reduce this serious threat to people around the world.

SUMMARY OF PhRMA's POSITION ON A COMPLIANCE PROTOCOL TO THE BIOLOGICAL WEAPONS CONVENTION

INTRODUCTION

As observers of recent international events, PhRMA companies join others who are convinced that biological weapons represent a serious and increasing danger to people around the world. PhRMA actively supports ongoing efforts to strengthen the existing Biological Weapons Convention (BWC) by the inclusion of measures to help assure compliance with the treaty.

Since many of the resources needed for a biological weapons capability are similar to those used in our industry facilities to discover, develop, and produce medicines, PhRMA accepts that any compliance protocol will involve industrial facilities. The provision of information about some of our facilities and the possibility of opening these facilities to inspections under some circumstances will need to be elements to the strengthening of the treaty. However, these elements also entail risks to commercial facilities including the potential loss of proprietary information, risks to commercial reputations, and added regulatory expenses that ultimately impact the cost and availability of medicines and other widely-used products. Therefore, PhRMA has developed the positions below. They represent an appropriate balance between what can be realistically gained through a compliance protocol and the risks to legitimate industry facilities that are necessary for the development and production of medicines and food. Further, PhRMA offers expert assistance to develop a Compliance Protocol to the Biological Weapons Convention that is technically feasible and scientifically sound.

BACKGROUND

The BWC prohibits the development, production, and stockpiling of biological weapons. Ratified by the U.S. in 1972 and in effect since 1975, the BWC does not include any enforcement mechanism. Signatory Governments decided in November 1996 to begin negotiating a Compliance Protocol to the BWC. Possible provisions of such a Protocol have been discussed and a "Rolling Text" containing multiple options is being discussed by the Ad Hoc Group of States parties.

THE PhRMA POSITION

The following discussion covers all the elements needed for a cost effective compliance protocol.

Declarations

Of the present voluntary measures intended to build confidence in compliance with the BWC, the only one applicable to commercial facilities is the requirement for Governments to declare (i.e., identify) producers of human vaccines licensed in their countries. PhRMA considers these measures lacking in their ability to demonstrate a country's compliance with the BWC, and therefore insufficient to truly enhance transparency. Government declarations should encompass those facilities of greatest relevance to the detection and deterrence of biological weapons. Facility declarations should be simple and not include any confidential business information.

It may also be appropriate to define a clarification process to enable the international secretariat to obtain answers to questions about declarations (including omissions). However, such a process does not necessitate any visits to facilities.

On-site Inspections Should be Limited to Challenge Inspections

PhRMA is skeptical that any site inspection can detect a violation of the BWC. The nature of microbiology is such that is easy to quickly obliterate traces of any development, manufacture, or storage of a biological-warfare agent. However, should there be an unusual outbreak of disease, evidence of a violation of the BWC or evidence of use of biological weapons, it may be appropriate for the international community to conduct an on-site challenge inspection. PhRMA does not support requirements for any form of non-challenge inspection. PhRMA does, nonetheless, support truly voluntary, educational visits.

Challenge inspections must be conducted according to due process in order to permit inspections where serious violations are alleged, but curtail frivolous or malicious inspections. This will help ensure that such essential industries as those involved in the provision of health-care and food are not compromised by improper or unsubstantiated claims of violations. Due process would include:

- The authorization to conduct a challenge inspection is determined by an affirmative, simple majority vote of the Executive Council of Government representatives.

- "Managed access"- under which site managers control access to different parts of a facility - is used during any on-site inspection. The aim is to help inspectors gain access to desired information while protecting the rights of a facility being inspected through a negotiated agreement between the two parties. A managed-access agreement would minimize the potential for loss of confidential business information. Procedures also must be devised to resolve disputes in cases where the inspection team and the facility to be inspected cannot agree on inspection terms.

- A private commercial enterprise has the right to make the final determination as to what constitutes confidential business information. This includes the right to deny specific requests for samples or photographs. An inspected facility remains under the obligation to acknowledge the questions of the inspection team and should use all reasonable alternate means available to satisfy the inspection team's request.

- In order to demonstrate compliance with the Protocol, the inspected party could share with the U.S. Government information it does not want to disclose to international inspectors. This would demonstrate that the determination of what is confidential information is being responsibly handled by the facility being inspected.

- The inspected facility receives a copy of the on-site inspection report and has the right to respond before its release. Further, in the absence of clear and convincing evidence of biological weapons development, production, stockpiling, or use, the report must state that the allegations could not be substantiated.

Training of Inspectors

PhRMA companies will offer educational visits to members of the international inspectorate. These visits will be designed by individual facilities. The US Government may offer educational visits to their own facilities based on the procedures to be found within the treaty.

CONCLUSION

PhRMA continues to be an active participant in working to reduce the threat of biological warfare. PhRMA is working with international negotiators to develop a compliance protocol that will fully protect the confidential business information and reputations of its member companies, which enables them to lead the world in discovering and developing new life-saving medicines while allowing inspections of facilities for which there is reason to suspect illicit activities. PhRMA will offer expert assistance to the U.S. Government to help ensure that any Compliance Protocol to the Biological Weapons Convention is scientifically and technically sound.

This document represents a summary of the three PhRMA Board positions taken in May 1996, January 1997 and May 1998.

Mr. SHAYS. Colonel Kadlec.

Colonel KADLEC. Thank you, Mr. Chairman, members of the subcommittee. It is a great pleasure to be here today, and it looks like I am the cleanup batter for today's panel. But before I begin my formal remarks, I'd like to remind you that I am here on my personal auspices, and my views are solely my own, not of the U.S. Government, Department of Defense, National Defense University, or the U.S. Air Force.

To give you a little background in terms of my reason to be here is that I served on the U.S. Delegation to the Biological Weapons Convention from 1993 to 1996, participated in several of the aforementioned U.S. department-sponsored trial inspections, and also served as a U.N. Special Commission inspector in Iraq in 1994, 1996 and 1998.

Mr. SHAYS. And, Colonel, right now you are a professor at the War College?

Colonel KADLEC. That's correct, sir.

Mr. SHAYS. So you are coming as a professor from the War College with your own views? Fine. Thank you.

Colonel KADLEC. Thank you. To maybe address specifically the issues that you raised in the letter that I received to attend today's panel discussion, the first and foremost was how did the United States develop a verification policy for the U.S. BWC protocol? I think Dr. Zelicoff's comments touched on maybe some of the more finer points, but I think in quick summation, the fact is we really didn't have a clear articulated strategy or approach for the negotiations, and that clearly had a partial paralysis on the events on the ground in Geneva. It clearly hamstrung the delegation to either accept or reject positions that were being offered. It certainly limited our ability to project positions in that—into national fora. And more significantly, I think it had an impact on limiting the kinds of things we could be doing back in the States, particularly national trial visits, that would have helped us understand the implications and consequences of some of these measures as being proposed.

I think it's just worthy to note that the Department—or Department trial visits that were conducted were sponsored by specific government departments rather than the U.S. Government at large, principally because there was no consensus, and certainly there was no endorsement of those trial visits and the reports and subsequent findings that came out of those. So in the end I think, simply put, we were very limited in what we could do.

As far as the current draft protocol and whether it would be possible or whether it would be able to detect or deter rogue nations or terrorist biological weapons activity, I would judge that to be a low probability. Two principal reasons, and one is inherent in the protocol and the other one is inherent in, if you will, the nature of biological arms. First, the protocol is certainly not comprehensive in its inclusion or coverage of facilities of concern. I think it's noteworthy that universities and many other facilities, food processing facilities, are not included in that, and that there are certain, if you will, arbitrary distinctions or criteria that exclude R&D facilities or even small possible production facilities. It's still a matter of con-

cern but would not be necessarily a matter of disclosure—voluntary disclosure through this protocol.

The second part is, it's certainly the ambiguities that are inherent in these activities. I always remind myself that the original drafters of this convention back in the mid-seventies, essentially seventies, did not include verification measures, not because they didn't want to, but because it wasn't easy, and certainly not clear then. And I would suggest that in some ways it is less clear today because of the advances in biotechnology that really provide great efficiencies and great capabilities in facilities that were not considered, or even unheard of back in the 1970's.

So with that as a backdrop, I would suggest that at least for detection purposes, we may be better off, as Dr. Rosenberg, to rely on our national capabilities within the intelligence community. And maybe that's where we would be better served to make investments to strengthen those capabilities that could detect those proliferators pursuing these weapons, particularly in the human intelligence side.

The issue of deterrence is a little more complicated, principally because, as you well know, deterrence is based on not only a capability but also a credibility of whatever tool you have, particularly in this case the protocol, and that would be the specific measures that it offers and the procedures that it offers as well. It goes without saying, it would probably—if it's unlikely to detect a cheater, it's probably unlikely, or very low probability, to deter a cheater. In that sense, I think, again, we may look to other investments to see if we can bolster our capabilities. And, again, if you look at this protocol as part of a larger national strategy, the technical side of this is such that I would probably defer to other means to give us confidence in whether or not the treaty is being complied to.

Your issue about the extent to which the protocol will improve verifiability of the BWC, I think it's a—I would say it would be bold to advocate, and I think it is the consensus here that it's probably not verifiable, but I would point out that there also may be an unintended consequence of this effort. And that is principally in if a state's party complies with the protocol, does that necessarily mean that they comply with the treaty? And that is a potential sleight of hand that could be used by countries that are certainly suspected of those intentions. Clearly in the course of negotiations, Iran was one country that tried to make a case—and it will be unclear until the end game whether they went out on this—that they could somehow trade, if you will, their compliance with the protocol with the abolition of multilateral export controls. And that is just one possible outcome that needs to be considered.

Finally, your last point is related; specifically, what additional mechanisms could be used to strengthen the effectiveness and improve implementation of the Biological Weapons Convention. And there are two. I would like to endorse the comments made earlier by Dr. Zelicoff and Dr. Rosenberg on the fact that it seems like an odd paradox that the treaty that is entirely devoted to the deliberative use of disease as a weapon does not have any provisions to either create, expand, or mandate systems to monitor disease occurrence. And this is clearly one area that probably deserves more consideration and certainly would be one that would—could objec-

tively not only strengthen our nonproliferation goals, but certainly strengthen our national and international public health objectives as well.

My last comment is directed to an issue that has been touched on lightly here, but certainly where my experience weighs heavily, and that is through the United Nations Special Commission. I would just like to point out that the verification of experts exercise that was conducted in the early nineties, that basically produced the foundation for the draft protocol and identified 21 possible measures both onsite and offsite that could be used to strengthen the compliance with the treaty, were actually all employed during the experience in Iraq.

What is interesting to note, and I guess in part it's maybe part of the cognitive distance that was existing in the U.S. Government, but certainly the fact that chronological experience was that they were parallel events that sometimes operated, I won't say completely independently, but certainly sometimes detached, and that is a systematic comprehensive review of the UNSCOM lessons: clearly what worked, what didn't work, and clearly making that as a benchmark to assess whether or not a future protocol—whether this protocol or any protocol could address these purposes.

Until, I think, we assess that and certainly conduct more government-sponsored trial visits, it will be very difficult, I believe personally, to negotiate or commit to any protocol that is both sensible or effective. Thank you, gentlemen.

Mr. SHAYS. Thank you, Colonel.

[The prepared statement of Colonel Kadlec follows:]

Written Testimony of Colonel (Dr) Robert P. Kadlec, USAF

To the Subcommittee on National Security, Veterans Affairs,

& International Relations of the Committee on Government Reform

Washington D.C.

5 June 2001

Mr. Chairman and members of the Subcommittee-It is both and an honor and pleasure to be here today, before I make my remarks, I am obligated to remind you that my views are solely my own and do not reflect those of the U.S. Government, the Department of Defense, National Defense University or the U.S. Air Force.

I have had the privilege of serving on the U.S. delegation to the Biological Weapons Convention from 1993 to 1996, participated in several Department sponsored trial inspections and served as a United Nations Special Commission inspector in Iraq in 1994, 1996 and 1998. With that as a background, I have experienced both the theoretical and practical aspects of biological arms control. In short, I tend to be a realist rather than an idealist as it pertains to this subject. To respond to your specific interests outlined in your letter of invitation I shall address them in order.

1. How the United States developed verification policy for the BWC Protocol?

Since the early 1990's, consideration of a protocol to verify or strengthen the BTWC has been a matter of some contention. There are main elements of the US Government and arms control communities that doubt whether verification of this treaty

is possible at all particularly to the standards the U.S. sets for verification. I would like to point out that the final report from the Ad Hoc Group of Governmental Experts (VEREX) refrains from concluding that the measures serving as the basis for the Chairman's text achieve verification but rather suggest that there may be a combination of measures that could contribute to strengthening the Convention.

Prior to the 1996 BWC Review Conference, there was a general but not necessarily a unanimous view in the U.S. that verification of the BWC was impossible. The lack of a clear USG consensus created an inability to develop a clear and unambiguous negotiating approach or strategy. This lack of a strategy resulted in a partial paralysis of US delegation during the negotiations that occurred during the Ad Hoc Group efforts to draft a protocol. This paralysis also manifested itself in efforts to conduct trial visits to test or assess proposed compliance measures. The few trial visits conducted were Department sponsored events, whose reports did not carry the sanction or overall endorsement of the U.S. Government. The end result was both a process and policy that hamstrung the BWC delegation. We could only work on the margins of the effort. It could neither commit to nor reject the outcome of the drafting exercise of what was being characterized by some other delegations as a "verification protocol." The term of art used by the US was to promote transparency and compliance with a protocol rather than verification. The substantive difference was that the measures contained in the draft protocol would permit

compliance with the protocol but would not necessarily ensure, with a high degree of confidence, compliance with the treaty itself.

2. The ability of the current protocol to detect and deter rogue nation and terrorist biological weapon activity.

I would judge that the draft protocol I have reviewed would have no better than a lo probability to detect and deter a would-be proliferator or terrorist seeking to develop biolo weapons. Much of what is contained in the draft protocol is based on voluntary submissio about select, non-comprehensive specific activities that could be characterized as ones of concern. Complicating any assessment of declarations or even visits is the dual-use nature the materials, equipment, and processes involved in biological warfare. This complication valid independently of the defect of having only a part of the universe of relevant facilities activities declared. Ambiguities are inherent in biological activities. This draft text does n nor cannot discern with a high degree of confidence, prohibited activities from legitimate o It is possible, but I judge unlikely, that submission of declarations or routine or transparency visits will provide the kind of direct unambiguous information needed to detect prohibited activity. I believe that the more probable scenario for detection of prohibited activities would result from efforts outside the protocol itself. National intelligence capabilities and programs, for example, would be more likely to detect possible violations than voluntary submissions by participating parties. Information from national capabilities would be crucial in triggering challenge type inspections. The

proposed Chairman's text does offer some reasonable measures to strengthen the existent treaty by creating provisions and procedures to investigate alleged violations through a challenge mechanism that is independent of the UN Security Council. If there is a modicum of deterrence to be gained from a future protocol, it is the inclusion of provisions to permit immediate and full investigation of possible violations to include accidental release of or actual use of biological warfare agents.

Even by adopting these challenge-based provisions, it will be particularly difficult to estimate what, if any, level of deterrence is achieved. Deterrence is based on the capability and credibility of the protocol - its instruments and procedures to increase the probability of detecting or catching a violator. It goes with out saying that if a future protocol is unlikely to detect cheating, the overall level of deterrence is probably low. In final analysis, I would contend an investment in national intelligence capabilities would result in a higher probability of detecting prohibited activities versus committing to a compilation of voluntary measures that may be potentially costly to implement and are likely to be ineffective.

3. The extent to which the protocol will improve the verifiability of the BWC.

In my judgment, enacting the draft protocol will not enhance the verifiability of the BWC. It is possible that a contrary effect may be achieved. If a state party is compliant with the protocol, does that necessarily mean that they are compliant with the prohibitions of the treaty? There may be an unintended outcome of this effort. Violators

of the treaty may find legitimacy and cover behind their compliance with the protocol. This potential paradoxical outcome may have greater consequence if the future protocol ensures that compliant parties cannot be subject to export controls or other sanctions. That is the intent, I believe, of countries like Iran to basically link compliance with a future protocol to the abolition of multilateral export controls like the Australia Group.

4. Additional mechanisms under discussion to strengthen the effectiveness and improve implementation of the BWC.

I consider it an odd paradox that for a treaty that is concerned with the deliberate use of disease as a weapon, it does not have any provisions to create, expand or mandate systems to monitor disease occurrence. Efforts to include specific measures to investigate and or report outbreaks of disease or provide assistance to do so under existing draft protocol have been largely rebuffed. It would seem to be both an essential and fundamental part of any future protocol. Creation of an open architecture system of disease reporting, one that provides transparency and confidence about disease occurrences that may have biological warfare concern would be an invaluable adjunct to a US strategy to counter these weapons. Disease surveillance would also have the added benefit of supporting existing national and international public health objectives.
The reluctance of the traditional international and national arms control communities to support this kind of proposal reflects, in part, the cultural as well as the technical differences represented by the nature of biological arms control. The process we have

witnessed so far, I believe, largely represents an extrapolation of measures enacted in the Chemical Weapons Convention. I do not believe as a Government or international community, we have studied, much less learned from the experience of UNSCOM in Iraq. The 21 measures identified by the VEREX effort were used there. It would seem to be an invaluable, if not, vital step to assess the success or failure of these measures to detect or deter one nation's efforts to pursue biological warfare. An important additional step is to validate those lessons learned during USG sponsored trial inspections under controlled conditions. Until we do both, I don't know how we can negotiate or commit to any protocol that is both sensible and effective. Thank you Mr. Chairman.

Mr. SHAYS. Mr. Schrock.

Mr. SCHROCK. Thank you, Mr. Chairman. Again, thank you all for being here. This is a frightening subject to me, and it's something I had not thought much about until I came to Congress. I was privileged to serve in the Navy for 24 years, and what we worried about in Vietnam were the Viet Cong; we didn't worry about chemicals and biological-type things. But I think the real enemy we're going to have now is that, and I don't know how the devil we get our hands around it, and I am concerned by that.

I have a comment for the Colonel, but I wanted to start with Dr. Zelicoff. When the administration officials last appeared before this subcommittee, one of the witnesses—I believe it was Ambassador Mahley—said, "the United States has never judged that the protocol would produce what is to us an effectively verifiable BWC."

In other words BWC is not verifiable. Help me understand what the technical meaning of "effectively verifiable" is and to what extent is it verifiable?

Mr. ZELICOFF. You will never get a U.S. Government agency to define what "verifiability" means. I have tried.

Mr. SCHROCK. I'm sure.

Mr. ZELICOFF. But I do believe that there is consensus, and I would hazard a guess there is even a consensus on this panel that verifiability has a certain minimalist standard, and that is that it's more likely than not to catch a cheater before he's able to do something disastrous with his biological weapons and—and this is equally important and always ignored—more probable than not, to not accuse somebody of violating the treaty when in fact no violation has taken place.

Now, as a scientist, we refer to those things as—we have terms for them. We call it the sensitivity and the specificity, but you can think of it as the likelihood that you miss something and the likelihood that you make a mistake by falsely accusing somebody.

With that minimalist definition—that is, both being able to have a more probable than not standard for finding a cheater before he's able to do something significant—I don't think that there is any question that the treaty does not—or the protocol does not meet that verifiability standard.

With regard to the more problematic issue, that is, falsely accusing somebody, what we learned very clearly in the U.S. trial inspections—which I have to say were conducted in a scientifically credible way, meaning that they were blinded, meaning that no one who participated as an inspector knew anybody who was at the inspected facilities, and other such reasonable precautions to prevent bias—what we learned clearly from those was that the probability of coming up with an ambiguous result—that is, walking away with less confidence that the site was in compliance—was actually the biggest problem.

In other words, it is highly likely that if a properly, or improperly I should say, politically motivated inspection team came to a U.S. pharmaceutical facility they could see anything they want to see and make a story that is completely in their view credible for biological weapons violation even when no such violation is taking place. That was precisely what happened to us when the U.S. trial inspections took place at a small vaccine facility in Michigan, a

very modest facility by comparison to the average pharmaceutical facility in the United States, and indeed the report of the team, which we were not allowed to release in Geneva, was that the team was less confident that the facility was in compliance after than before visiting.

So on those two standards of verifiability I think the trial inspection experience is clear, false positives and false negatives are very, very likely. Thank you.

Mr. SCHROCK. If it isn't verifiable, why have a protocol?

Mr. ZELICOFF. That is not for me, I assume.

Mr. SCHROCK. It will stop shortly.

Mr. ZELICOFF. It depends on what your goals are of course. If your goal is verifiability, then you should not believe or sign up to a protocol like this because it doesn't deliver the goods. If the goal is something less than verifiability; for example, improving confidence, then one can select among the measures that are available that I think over time would generate an increased belief of the credibility of the enforcement of the treaty. But now we start to get into judgments that as a scientist I am not prepared to make.

Mr. SCHROCK. Colonel, I am probably going to paraphrase here and I like a comment I think you made, you said rogue nations are likely not to use chemical-biological warfare. Did I misread you? I thought I would sleep better tonight because of that.

Colonel KADLEC. No, sir, I did not say that and I wouldn't endorse that at all. My apologies if I left you with that impression.

Mr. SCHROCK. Well, I'm glad you cleared that up, but I'm sorry it's not true.

That's all, Mr. Chairman.

Mr. SHAYS. We have had two visits to Geneva, we have had one other hearing and we have had a lot of research done and we have had the GAO and others report to us on this issue, and I am left with a feeling myself after this brief kind of introduction to this issue, I don't honestly know how you verify. And as we start to go through the panel I got the feeling, Dr. Zelicoff, that you don't like the BWC protocol as written and that you wonder whether you can verify. Dr. Smithson, I get the feeling you don't like the protocol as written but you think something needs to happen. Dr. Rosenberg, I get the feeling that you are very strongly supportive of the protocol and you think it is clearly the way to go. And Dr. Woollett, I get the sense that you don't want verification inspections. That's the general sense I get. And Colonel, I get the sense that you don't think the BWC protocol will work. That is the general sense. So it is kind of like in a scale here, panel, three against one—kind of against but something needs to happen, and one and four.

Ms. ROSENBERG. Can I correct what you said about me? It is not exactly correct.

Mr. SHAYS. I understand. It may be that all of them aren't correct. By the way, any question that I ask one any of you are more than welcome to respond to. Before you take that, maybe any comments that any of you wanted to make to the previous questions that were asked, if you wanted to jump in to respond to the questions that my colleague asked. Why don't we start there and then we will deal with my summation of where you stand. Anybody want to jump in on anything that was asked?

Ms. ROSENBERG. On the question he asked?

Mr. SHAYS. Yes.

Ms. ROSENBERG. Yes, you asked why—if verification is impossible why bother with the protocol? Because the protocol does something else, as I tried to point out. It can raise suspicion or it can allay suspicion, it can increase confidence. It increases transparency, and this is something that is not verification in the strict sense, where you prove that there is no violation or full compliance, but it adds to all the other national capabilities that we have. It is an additional tool.

It has been pointed out there is a web of deterrence that involves a series of different things like export control and national intelligence, military preparedness, defense, and the protocol is another tool in that web which gives us additional capabilities and feeds in so that it helps us to focus our intelligence on the facilities that might not have been recognized as being a problem but that something might come up, or to eliminate bothering with some that we feel convinced are OK as a result of protocol procedures.

Ms. SMITHSON. I would like to address the question about whether or not we can go forward and should we go forward with this. At present we are dealing with from the U.S. perspective really two data points. The two trials that the United States has conducted I think are certainly the most robust ones that have been conducted internationally. And what worries me is we have incorrect data points in that we seem to be throwing up our hands at this juncture. When you can't figure out something, quite frankly you try harder to figure it out. And the technical experts who sat at our table were certainly very familiar with what inspections were all about, especially those from industry. Those are individuals who have inspectors in their plants all the time. They get no-notice inspections. They get inspectors there for weeks at a time and they know how to make things work for the host facilities and for the inspectors. And I'll take their advice on this. They are encouraging the U.S. Government and industry to actually get out there and do the grunt work required to figure this out, conduct the field trials, work harder.

Ms. WOOLLETT. I think I have to make a comment at this point that PhRMA has expressed a willingness over a number of years. But what are we actually modeling? If we have to model some method by which we prove ourselves innocent for the reasons that Al Zelicoff has discussed earlier, that is simply not doable. Our capabilities, should we be so inclined, are so much more than would be needed. There is no way we can prove that we haven't ever made a BW. We can affirmatively show what we do indeed do. We can show we can make medicines but we can't show that we haven't used the facilities for illicit purposes. So the moment you have a lack of presumption of innocence, no facility, however capable, can prove it hasn't made BW. So I think this is the fundamental quandary as to what actually inspections are for. That's what the text doesn't resolve, particularly in terms of its routine inspections.

Mr. SHAYS. Dr. Rosenberg, you wanted to respond to my characterization.

Ms. ROSENBERG. Yes. You said that I, and I presume my group, are strong supporters. We are supporters of a protocol. The chairman's text is a good deal weaker than we would like to see, much weaker. We know there could be a much better protocol out there, there could have been. The problem though is not technical. It is political. This is the best protocol we can get at this time and for some time to come, and it is better to have something than nothing because otherwise we are telling proliferators that they can go ahead with impunity.

Mr. SHAYS. I am going to use Dr. Zelicoff's comments to generate dialog with the four of you. It doesn't mean, Dr. Zelicoff, you can't comment either. First I am going to read: You said, doing something should never be confused with doing something useful. But—this is a long paragraph but I would like you to listen to it and then I would like you to comment on it. You were referring, I am on page—no pages, doctor; you automatically drop from an A to a B if I were grading you. I have no pages on this. But at any rate, despite these valuable results the process of policy development with U.S. Government protocol negotiations soon faltered. You say it is not a very well kept secret that there was intense friction between the Security Council by the entirety of the Interagency Working Group on Biological Weapons Control through the past 8 years while the policy was under development. Then you say essentially nothing in the way of tangible policy was put forward during this time because one or at most a few low level staffers within the NSC sought to suppress the results of the mock inspections, break interagency consensus on negotiating strategy and impose an extraordinarily ill-suited vision for the BWC protocol which was make it like the Chemical Weapons Convention.

I'm still going to read on. Nothing could be more wrong-headed for all the reasons that you have heard in last September's testimony; nothing could be more destructive for the future of the BWC. There is no question that there was a complete absence of serious administration attention to the negotiations taking place in Geneva. Otherwise, the grating questions about goals and tactics that haunted all members of the delegation for all of the last 8 years would have been resolved. That low level NFC functionaries were able to force gridlock speaks volumes about the lack of leadership for and periodic review of the U.S. negotiating stance throughout most of the 1990's.

I will just tell you this summarizes my feeling about my observation of the negotiations that have taken place during the time that I followed, and I have no sense ultimately of what we hope we can achieve, frankly. But let me ask you to comment on this, all of you. First, Dr. Zelicoff, do you still believe this?

Mr. ZELICOFF. I do, sir.

Ms. SMITHSON. I would applaud Dr. Zelicoff's candor, as someone who spends a great deal of time watching the U.S. Government attempt to make decisions and often bumbling what they do. His description here I believe is right on target, so I will agree with it in total.

Ms. ROSENBERG. I did talk about this in my written testimony. I agree. I think we all recognize that there was no high level leadership during the course of these 6 years of negotiations, that al-

though President Clinton issued several statements in support of the goal, no one at the top levels pushed it. It was left in the hands always of lower level officials. And in the interagency group each one had his own turf to protect and nobody took the common interest as an overview, and I think that is a very sad commentary on our government.

Mr. SHAYS. Dr. Woollett.

Ms. WOOLLETT. I think your question of what do you achieve is absolutely critical because this will be a balance of what is put at risk, what is the burden, what is the cost on whomever verus what you achieve. We're able as industry to assess the risk to our patients, to our products. What we don't understand is the arms control aspects. What would this do for global confidence that we wouldn't have if we were left with just the treaty, which, remember, is those people who've agreed not to do this stuff in the first place. So we are only talking about a subset of the world anyway.

So our question is fundamentally the same as yours: What would you achieve with this protocol that you wouldn't have otherwise?

Colonel KADLEC. Sir, I would concur with Dr. Zelicoff's assessment. I would add, and again to expound on the point of the chemicals weapons inspection, that there seem to be, and again this is one of the cultural-technical differences between the two communities of chemical versus biological processes that seem to get often blurred, which is somehow you can take it by direct extension and extrapolate it to the biological processes, which I think is fallacious, and I think Dr. Zelicoff pointed that out.

I would also add that there was a certain level of idealism here that somehow you can go much further than you could with this. And I would like to go back and address the point made earlier, the question asked earlier about why have a protocol and certainly Dr. Smithson's point about specifics as it relates to doing national trial visits. You may or may not recall a place called Al Hakam, but that was a facility that the Iraqis declared in 1991 after the Gulf war. It was the site of intense scrutiny by the U.N. Special Commission over a number of years, thought to be very suspicious because of the nature of the layout, physical features. It was dispersed, there were unground bunkers, there were anti-aircraft sites around it. But it was not until 1995, despite numerous challenge, routine monitoring inspections of that facility that truly the clear intent behind that was known based on Hussein Kamel's defection. And I just highlight that as one of those key points, that if you use traditional arms control approaches, as we do in other disciplines, I think you will come up short. And in fact in some ways you may wish to reserve those capabilities. And when you look at a protocol it would seem the challenge mechanisms that allow you to get to the kind of situations that were encountered in Sverdlovsk in Russia in 1979 or certainly if there were an equivalent occurrence of the use of chemical weapons in Iraq or against Iranians, that there would be a mechanism outside the U.N. Security Council to ensure that those things could be promptly and fully investigated.

Mr. SHAYS. You made reference to an individual. Was that one of Saddam Hussein's son-in-laws?

Colonel KADLEC. Son-in-laws.

Mr. SHAYS. And what we learned from both of them coming forth was that there was a site that was not disclosed?

Colonel KADLEC. Well, sir, Al Hakam was disclosed. It was declared by the Iraqis, but the true intent and purpose behind that site was never known.

I left out one important piece of the story because during the course of the 4-year, if you will, monitoring by UNSCOM the Iraqis actually were building a new site on that facility that gave it an incredible fermentation capacity of 50,000 liters and this was done under the watchful eyes of UNSCOM. It was given a nominal cover, if you will, of being a single cell protein facility to make cattle feed, for which everyone suspected that was not indeed the case but the smoking gun was elusive, and even under the most stringent provisions that were ever created for arms control through the UNSCOM and through the U.N. Security Council Resolution 687, that was not really appreciated until someone from the inside came out to basically disclose what the purpose of that facility and site was.

Mr. SHAYS. We do have a clock on now, but Mr. Tierney has joined us and I am eager to have my colleagues jump in. But let me make sure that I am not, that we are spelling it out. Is it your testimony before us that without an insider you could basically disguise the use of the facility even with the inspections?

Colonel KADLEC. Sir, again that's the practical experience that came out of that episode. I think again Dr. Zelicoff touched on the point of intent, that it is very difficult to look at a fermentation kettle that is used for vaccines that may well be used in 7 days or 7 hours after the inspection team leaves to produce something other than a benign vaccine, and again it is the dual use nature of the problem.

Ms. ROSENBERG. I have talked with some of the inspectors who entered that single cell protein plant, so called, and who said they only had to step inside to recognize that this was something much more than a single cell protein plant. They didn't know exactly what it was and we did not find that out until after the defection. But the point I would like to make is that we knew Iraq was up to something. We knew we had to keep our eye on them. And that is the kind of thing that the protocol can do. It will not give us the full answer, but the important thing is that we watch them so they don't go beyond.

Mr. SHAYS. Dr. Smithson, did you have a response? Dr. Rosenberg, I am sorry, I am going to ask you to repeat your last point. I got distracted.

Ms. ROSENBERG. I said that I have spoken with inspectors with UNSCOM who entered that single cell protein plant that Bob mentioned and they could tell immediately that plant was something more.

Mr. SHAYS. I got that part but then you made another point.

Ms. ROSENBERG. Yes, and even though they did not know exactly what it was for they knew that the Iraqis were lying. They knew they were up to something and they knew enough to keep their eye on it and to keep looking and to focus on preventing them from using that plant for some illicit purpose, which they succeeded in doing.

So I think this is a good example of what the protocol can do. It may not give us the full answer but it raises suspicions that will allow us to keep our attention on possible trouble points.

Mr. SHAYS. I will let both of you respond, but I have an observation, that I am wondering if only the human intelligence can detect the wrongful intent of violating the BWC. In other words, there are building signatures and you can't determine intent, say, from a satellite photo or hear intent on an e-mail interception. It seems to me that you almost need an insider to say bad things are happening here. Without that insider you are going to have a problem.

Ms. ROSENBERG. An insider or an inspector from a regime like the protocol would set up.

Mr. SHAYS. Because I think that an inspector, they close down the operation.

Ms. ROSENBERG. But that doesn't matter, you see. We are not doing anything I believe at this plant that Bob mentioned. You don't have to see it operating. It's capabilities that count. It was much too, what's the word, it had capability that wouldn't be needed to make single cell protein. It was much too elaborate for that. And the inspectors immediately recognized that this could be used for something other than what they said it was.

Mr. SHAYS. I am going to jump both of you for a second, but the bottom line is isn't that the problem. My limited understanding of this issue is if you have dual uses it can be used for something other than a legitimate use.

Ms. ROSENBERG. That's right, but the point is you have to declare in a regime—like the protocols, you have to declare what is the use and there's evidence. If you say you're making a pharmaceutical you can find out what's on the market that is coming out of that place, you see. So you have a lot of other evidence with which to compare the capabilities and if they are beyond what are needed that raises suspicions. So all right, you don't bomb them, but you keep an eye on them.

Mr. SHAYS. Mr. Tierney.

Mr. TIERNEY. I just want to followup on that. You go on. I am looking at some of the comments that Ambassador Mahley made not too long ago. There is a real value in increasing the transparency associated with biological activity. This could in our view complicate the efforts of countries to cheat on their Biological Weapons Convention obligations. The United States believes investigations are one of the most essential elements of a BWC transparency regime. Actually talking to scientists and production workers on the ground as well as observing the atmospherics at a facility are ways for experienced observers to detect anomalies. One can never discount either the whistleblower prospect of an employee or the ineptitude or a coverup of an illicit activity. While there is no likely way to judge the likelihood of such an outcome, the deterrence component is useful since it complicates the life of a potential proliferator.

I see in that what you are talking about, but I also wonder what has changed in the Bush administration to all of a sudden back off these comments made by the Ambassador. What's happened in the interim on that? Why is that still useful? We understand that they are not fool proof and they're not absolute, but there are advan-

tages in moving in this direction. And what has changed on that and why would they pull their witnesses today, who would be able to expand on that? And Ambassador Mahley might be able to tell us if in fact he has had a change of heart there.

Ms. ROSENBERG. Well, I think we have to consider the possibility that this administration's policy here is not determined by the logic of this particular situation but by an ideological view of arms control in general, particularly multilateral.

Mr. SHAYS. Dr. Rosenberg, in all fairness before Mr. Tierney came here you acknowledged that for the last so many years there has been no movement forward.

Ms. ROSENBERG. I did, yes.

Mr. SHAYS. Let me just finish this one question.

Ms. ROSENBERG. Let me say a pox on both your parties. I think the common interest calls for doing something on biological weapons and I don't think either party is pushing appropriately. I am not standing behind either one.

Mr. SHAYS. Mr. Tierney asked if I was happy now. Let me have both of you respond.

Ms. SMITHSON. I too have spent a fair amount of time in the company of individuals who served on the United Nations Special Commission inspections. One of the things they told me time and again, as well as the individual who went into Soviet facilities, is that literally the minute they walked in the door they knew they were in the midst of something that didn't walk and quack like a duck. In other words, they were in the middle of biological warfare facilities, and that is one of the most important things that these inspections may be able to tell us if we actually figure out the right way to do them.

As for the application of the satellite assets and SIGINT and MAZINT and other types of capabilities, I fear your suspicions are probably correct. We may not be able to tell as much from those capabilities as we might have been for other types of weapons of mass destruction. And in terms of work that was done in our brainstorming sessions, one of the things that all groups of experts that sat around our table consistently pointed out is that if inspectors went in the door one of the things they would look for would be inconsistencies with a stated purpose. This would be waste treatment capabilities beyond the needs of the facility, containment capacities beyond the needs of the facilities or less than what they stated they needed, or other types of activities or capabilities at a site that simply didn't fit with what they said they were doing, in their multiple ways that these experts from industry, from research institutions believed that this could be tracked through monitoring procedures. We just need to work harder to figure that out.

Mr. SHAYS. Dr. Zelicoff, do you want to make a comment? Did you forget what it was that you wanted to make? It was a while ago.

Mr. ZELICOFF. I don't think so. I have to respond to several things that Barbara said because I think we are going down a path——

Mr. SHAYS. You have to use last names. I am not on a first name basis, so I am forgetting who Barbara is.

Mr. ZELICOFF. Dr. Rosenberg.

Mr. SHAYS. I'm sorry, I would like to be on a first name basis with the doctor, but not yet.

Mr. ZELICOFF. We are going down a path that I don't think is particularly useful for the work of the committee. When I was practicing medicine we had a diagnostic tool that was 100 percent likely to find a disease, and it was called the 20–20 retrospectroscope. We would practice it all the time, and I am afraid that is what we are hearing right now with regard to the Iraqi UNSCOM program. Let's be clear, but for the defection of Kamel Hassan we would not have had any idea of where to look and what to look for.

Mr. SHAYS. I might say he was a whistleblower that had his head chopped off. Disincentive to whistleblowers.

Mr. ZELICOFF. That is correct. But even if it were true that we could go into a facility and smell something rotten, I want you to consider that biotechnology has advanced enormously in just the past 5 years. I suspect that if the Iraqis are carrying out a biological weapons program or if the Russians are carrying out a biological weapons program, they are not doing it like they did it even 5 years ago. Large scale fermenters, facilities for waste treatment, all of that is passe. It is completely irrelevant and this is simply because of the advances in the modern tools of biotechnology which require no large scale facility, don't require any special kind of equipment and could easily be done in a laboratory that would be a tenth the size of this room. Indeed, the Russians in particular have adopted what they call a just in time philosophy for biological weapons. They no longer brew up large batches of anthrax in enormous fermentation facilities. Rather, if the need should arise, the Russians plan to make their biological weapons en route to the front on rail cars. Small facilities can take tiny amounts of biological material, a few organisms, and have hundreds of pounds of organisms like anthrax in just a number of days.

Now let me return to something Mr. Schrock said because I think this is the way the committee ought to look at the utility of a measure being proposed in the current chairman's text. Whenever a measure takes place, it is very much like a medical diagnostic test. So I will give you an analogy that I think is apropos here. That is to imagine doing a cardiac stress test on everybody sitting up there. I will lay you dollars to doughnuts, and that would include the people sitting along the wall, that at least one of you will have a positive cardiac stress test. Does that mean that person has coronary disease? Absolutely not, because the test has about a 5 percent false positive test. So if you do it 10 or 20 times it is improbable that you not get a positive even though the person does not have a coronary disease.

I state this to emphasize an important point. When you carry out a measure or combination of measures and call those measures a protocol, there are three possible outcomes. The protocol could make the treaty better. The protocol could have no effect whatsoever on the treaty. The protocol could make the treaty worse. How could it make the treaty worse? By generating numerous false positives that both undermine the political consensus for the treaty as well as undermine the technical validity of those tests. This is precisely why Ambassador Mahley referred to certain measures that could be useful for increasing confidence but they do not meet

the standards that we associate at least minimally with verification.

In particular, I think I want to summarize the one point that I think everybody on the panel agrees on. We can make the Biological Weapons Convention and the world a much better place if we can somehow enhance disease monitoring. I think that is obvious how that will help public health. But to address Mr. Schrock's point, will it verify the convention? No. However, on those rare occasions, like what happened in Sverdlovsk in 1979, when there is an accident or an experiment gone awry, or even a potential test of a biological weapon, should disease take place in either animals, human or even in plants, I am as confident as I can be about anything in science in saying that I am quite certain that the tools of modern epidemiology can separate a naturally occurring event from a man-made or intentional event. Will that verify the treaty? No, because those episodes are rare. In fact to the best of my knowledge, we have only had one. However, what it will do is set us down the path of enhancing disease monitoring, which will indeed complicate the activities of someone who wants to violate the treaty because ultimately they will have to test.

Mr. SHAYS. Interesting point, but if we are disease monitoring then the disease has already taken root.

Mr. ZELICOFF. Correct.

Mr. SHAYS. Mr. Tierney, you have the floor for as much time as you want.

Mr. TIERNEY. Thank you, Mr. Chairman. Thank you for having these hearings. I will just ask the chairman one question. I am a little late in getting here and I apologize for that. First of all, have the testimonies of Ambassador Sheaks and Ambassador Mahley that were submitted for the panel that did not occur, have they been put on the record yet and, if not, may we by unanimous consent put them on the record?

Mr. SHAYS. Sure, we will put them on the record; just note that they weren't put under oath but the testimony is obviously submitted by them and they will be put on the record. Without objection, so ordered.

[The prepared statements of Ambassador Sheaks and Ambassador Mahley follow:]

Testimony of Dr. O.J. Sheaks,
Assistant Secretary of State for Verification and Compliance, before the
Subcommittee on National Security, Veterans Affairs, and International Relations
Committee on Government Reform
U.S. House of Representatives

June 5, 2001

Thank you, Mr. Chairman.

It is both an honor and a pleasure to address the Subcommittee today on the issue of the negotiation of a protocol to the Biological Weapons Convention (BWC). Since Ambassador Mahley, the head of the U.S. delegation, is addressing his remarks to the current status of the negotiations, I will focus instead on the issue of verifiability – specifically, whether any protocol would improve the verifiability of the Biological Weapons Convention.

The BWC is inherently difficult to verify. The problem stems from the language of the Convention (which hinges on intent) and the nature of biology and biological weapons. Any protocol must grapple with the same inherent verification problems.

The BWC does not establish a formal international mechanism for verifying compliance. Instead, it relies upon self-policing by the States Parties to the Convention. If a State Party identifies a compliance breach by another State Party, it may pursue this concern through bilateral consultations or it may lodge a complaint with the UN Security Council

which in turn may initiate an on-site investigation. In practice, the self-policing system labors under two fundamental limitations.

First, assessing compliance with the BWC requires detailed information on the intent of biological programs and activities. The BWC prohibits the development, production, stockpiling, and acquisition of biological agents and toxins for *hostile* purposes, but it does not prohibit such activities if conducted for *peaceful* purposes. In fact, the BWC not only allows peaceful work utilizing the very substances that it was designed to control, it encourages such peaceful applications. Since almost all biotechnology activities are dual-use in nature, both they and the facility at which they are conducted can be used for legitimate purposes or for offensive biological warfare purposes. This requires a judgment as to whether the intent of a dual-use activity is legitimate or illicit. Intent is very difficult to determine, and typically requires detailed information from sources who had direct knowledge of the purpose of a program. National intelligence, such as from human sources, is essential to detect violations of the BWC. However, such information is often very difficult to collect, and its availability is unpredictable at best and, perhaps, wholly fortuitous.

Second, the nature and scale of biological weapons activities preclude readily identifiable external signatures. Whereas many tons of chemical agent are needed for a militarily significant chemical warfare capability, a comparable biological warfare capability would be measured in pounds of agent. Furthermore, the equipment needed to produce such amounts of biological agent could be housed in a relatively small space inside a

building without specific distinguishing features. Given the potentially small-scale and unremarkable features of biological production, the physical signatures that aid us in verifying compliance are simply not present for biological weapons. In the absence of physical signatures, once again it is necessary to acquire detailed information from sources who had direct knowledge about the location and nature of illicit biological warfare activities.

These two fundamental considerations virtually preclude the achievement of an effective international verification regime. An international BWC organization would not be able to collect the detailed intelligence information essential for uncovering illicit intent. Moreover, the absence of external signatures at biological warfare facilities makes it impossible to identify all of the facilities capable of conducting illicit biological warfare activities so that they could then be made subject to declaration and routine inspection. As a consequence, a protocol would not improve our ability to effectively verify compliance with the BWC either in terms of certifying that a country is in compliance with, or in violation of, its obligations.

The U.S. Government has consistently recognized the inability of any protocol to improve the verifiability of the BWC. This position was reaffirmed by the previous administration before the negotiations began in 1995. Instead, the goal established by the previous Administration was to promote measures that would provide some degree of increased *transparency* of potential biological weapons-related activities and facilities.

I will refrain from commenting on the level of transparency achieved in Chairman Toth's Composite Text and on the potential value of that transparency. Instead, I will provide my views on the key components of the Chairman's Composite Text -- national declarations, visits, and challenge investigations -- and explain why they would not improve the *verifiability* of the Biological Weapons Convention.

The Chairman's Composite Text would require annual national declarations of biological activities in the following areas: biodefense, maximum and high containment laboratories, work with listed agents and toxins, and microbiological production facilities. The criteria for declaration are of necessity highly selective and, as a result, only a small fraction of the pool of facilities in a country that could potentially be used for offensive biological warfare purposes would be declared. It is simply impractical to declare all potential dual-use facilities as these would encompass beer brewers, yogurt makers, and many academic laboratories. Furthermore, it is an analytical certainty that states conducting offensive biological warfare activities will either not declare such facilities, or will embed illicit activities at declared facilities beneath an effective cover of legitimate biological activities.

The Chairman's Composite Text also provides for an annual series of so-called "Randomly-Selected Transparency Visits" to declared facilities. As their name suggests, these visits are intended to enhance *transparency* and not to improve our ability to verify compliance or non-compliance with the Convention. These visits are directly tied to the annual declaration submission and, therefore, suffer from the same verification

failings. Only a small-fraction of the facilities potentially relevant to conducting offensive biological warfare activities would be subject to visits on a random basis. Even at visited facilities, illicit work on biological warfare could easily be concealed or cleaned up, rendering it highly improbable that international inspectors would detect evidence of non-compliance. Moreover, violators could remove any risk associated with such visits by engaging in illicit biological warfare activities at non-declared facilities.

Finally, the Chairman's Composite Text establishes a challenge investigation mechanism for addressing violations of Article I of the BWC – the central prohibitions of the Convention. There are two types of challenge investigation in the Chairman's Text. The first type is a "facility investigation" conducted at a particular facility to address concerns that it is engaged in biological warfare activities prohibited by the Convention. The second type is a "field investigation" of the release of -- or exposure of, humans, animals or plants to -- biological agents or toxins in violation of the Convention. Field investigations encompass allegations of biological weapons use and, in addition, concerns about an accidental release of biological agents or toxins or suspicious outbreaks of disease connected to prohibited biological warfare activities.

Generally, challenge investigations could help to deter cheating. However, they have inherent limitations. The inherent delay in securing approval for the investigation request from the implementing organization and in getting an investigative team physically on the ground would likely permit more than enough time to clean up or otherwise conceal evidence of a BWC violation. In addition, the dual-use nature of biological activities

and equipment could readily be exploited by a violator to "explain away" any concerns, with "managed access" rights available as a last resort to deny access to any incriminating evidence.

Let me sum up. Irrespective of whatever transparency value a protocol to the Biological Weapons Convention might provide, it would not improve our ability to verify compliance. The dual-use nature of biology and the advance, as well as worldwide spread of biotechnology, have conspired to make the BWC not amenable to effective verification, especially by an international organization. However, it is possible to determine that a country is conducting an offensive biological weapons program. In fact, after years of compiling intelligence information, the United States established that the Soviet Union and Iraq were engaged in such activities. National intelligence, particularly from human sources, is essential to detect BWC cheating. U.S. efforts to strengthen the Biological Weapons Convention should always proceed from that fundamental reality.

Thank you, Mr. Chairman.

TESTIMONY OF AMBASSADOR DONALD A. MAHLEY
SPECIAL NEGOTIATOR FOR CHEMICAL AND BIOLOGICAL ARMS CONTROL
DEPARTMENT OF STATE

BEFORE THE HOUSE GOVERNMENT REFORM COMMITTEE
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS
AND INTERNATIONAL RELATIONS
THE BIOLOGICAL WEAPONS CONVENTION: STATUS AND IMPLICATIONS

5 JUNE 2001

MISTER CHAIRMAN. IT IS MY GREAT PLEASURE TO REAPPEAR BEFORE YOU TODAY TO DISCUSS THE CURRENT STATE OF PLAY IN THE ONGOING NEGOTIATIONS FOR A PROTOCOL TO THE BIOLOGICAL WEAPONS CONVENTION (BWC). YOU WILL RECALL FROM MY PREVIOUS APPEARANCES BEFORE THIS SUBCOMMITTEE THAT THE UNITED STATES IS PURSUING AN OUTCOME THAT WILL STRENGTHEN THE CONVENTION AND AID IN EFFORTS TO COUNTER THE BIOLOGICAL WEAPONS THREAT IN THE WORLD.

THERE HAVE BEEN SEVERAL PRESS STORIES OVER THE LAST MONTH CONCERNING THESE NEGOTIATIONS, WHICH MAKE A NUMBER OF CLAIMS BOTH ABOUT THE POSITION OF THE UNITED STATES AND THE PROSPECTIVE OUTCOMES FOR THE NEGOTIATIONS. I WOULD LIKE TO TAKE THIS OPPORTUNITY TO CLARIFY SOME OF THE INFERENCES THAT MAY HAVE BEEN DRAWN FROM THOSE STORIES.

FIRST OF ALL, THE UNITED STATES HAS BEEN VERY CLEAR THROUGHOUT THE NEGOTIATIONS. WE UNRESERVEDLY SUPPORT THE BIOLOGICAL WEAPONS CONVENTION THAT UNDERPINS THESE NEGOTIATIONS, AND WE HAVE A STRONG DESIRE TO SEE THE ABILITY TO COUNTER THE GROWING BIOLOGICAL WEAPONS THREAT IN THE WORLD ENHANCED. THE UNITED STATES IS NOT THINKING ABOUT WITHDRAWING ITS SUPPORT FROM THE BIOLOGICAL WEAPONS CONVENTION, AND SUCH IMPLICATIONS ARE ABSOLUTELY FALSE AND UNFOUNDED.

IT IS SOMETIMES DIFFICULT TO UNDERSTAND THAT THESE NEGOTIATIONS ARE FOR A PROTOCOL THAT IS TO BE SUPPLEMENTAL TO THE UNDERLYING CONVENTION. THE NEGOTIATIONS ARE ONLY OPEN TO STATES PARTIES TO THE CONVENTION, STATES THAT HAVE ALREADY FORSWORN BIOLOGICAL WEAPONS COMPLETELY. THE MANDATE FOR THE PROTOCOL NEGOTIATIONS SPECIFICALLY PROHIBITS ANY RESULT FROM MODIFYING, REDUCING, OR ALTERING THE BASIC OBLIGATIONS OF THE CONVENTION ITSELF. THUS, THE COMMITMENT OF THE STATES PARTIES TO THE BIOLOGICAL WEAPONS

CONVENTION, INCLUDING THE UNITED STATES, SHOULD NOT BE ALTERED THE OUTCOME OF THE PROTOCOL NEGOTIATIONS.

THE NEGOTIATIONS HAVE PROGRESSED SINCE THE LAST TIME I APPEARED BEFORE THIS SUBCOMMITTEE. WHILE THE "ROLLING TEXT," A SET OF NATIONAL NEGOTIATING POSITIONS LOOSELY CONNECTED BY AGREED ELEMENTS OF A PROTOCOL, STILL EXISTS, NEGOTIATION ON THE BASIS OF THAT TEXT HAS NOW BECOME STERILE. THOSE ISSUES AMENABLE TO DRAFTING IMPROVEMENT OR INTERNAL COMPROMISE HAVE BEEN SETTLED. THE REMAINING ISSUES REFLECT SUBSTANTIVE DIFFERENCES AMONG COUNTRIES TO WHICH THOSE COUNTRIES ATTACH IMPORTANCE. THUS, IN A DISCUSSION OF DETAILED TEXTUAL PROPOSALS ON A SINGLE ISSUE, COUNTRIES HAVE BECOME UNWILLING TO RELINQUISH THEIR POSITIONS WITHOUT IDENTIFYING SOME COMPENSATING GAIN ELSEWHERE. WHEN THAT STAGE OF NEGOTIATIONS IS REACHED, THE ONLY WAY TO ACHIEVE FURTHER PROGRESS IS TO FIND A WAY TO OVERARCH INDIVIDUAL ISSUES WITH A MORE COMPREHENSIVE SOLUTION THAT MAKES THE TRADEOFFS BETWEEN ISSUES.

THE AD HOC GROUP CHAIRMAN, TIBOR TOTH OF HUNGARY, HAS ATTEMPTED TO DO THIS WITH THE "COMPOSITE TEXT" HE INTRODUCED AT THE LAST NEGOTIATING SESSION. IT IS A TEXT DESIGNED TO MAKE NO COUNTRY REALLY HAPPY, BUT TO OFFER SIMULTANEOUS WAYS FORWARD ON THE FULL RANGE OF COMPETING NATIONAL ISSUES AND NATIONAL POSITIONS.

AS I INDICATED TO THE OTHER AD HOC GROUP PARTIES DURING THE LAST ROUND, THE UNITED STATES HAS A NUMBER OF SUBSTANTIVE AREAS IN THE "COMPOSITE TEXT" WHERE LONG-CHERISHED NATIONAL NEGOTIATING POSITIONS OF MANY COUNTRIES HAVE NOT BEEN INCORPORATED. WE HAVE SERIOUS SUBSTANTIVE CONCERNS WITH THE TEXT AS AMBASSADOR TOTH PRESENTED IT. THE UNITED STATES BELIEVES MANY, IF NOT ALL, OF THE OTHER PARTIES TO THE NEGOTIATION WOULD MAKE THE SAME STATEMENT. THAT IS THE NATURE OF MULTILATERAL DIPLOMACY. THE QUESTION THAT HAS NOT YET BEEN ANSWERED IS WHETHER THERE IS ENOUGH SUBSTANTIVE AND POLITICAL UTILITY IN THE "COMPOSITE TEXT" TO ALLOW THE UNITED STATES TO ACCEPT AND SIGN THIS TEXT DESPITE THE SUBSTANTIVE CONCERNS WE STILL HAVE WITH IT. I WOULD REPEAT THE UNDERLYING PRINCIPLE OF THE UNITED STATES APPROACH TO THIS NEGOTIATION: WE SEEK IMPROVEMENT IN THE ABILITY TO IMPEDE THE THREAT AND REALITY OF BIOLOGICAL WEAPONS PROLIFERATION IN THE WORLD. WE RECOGNIZE THAT THERE IS SOME RISK INHERENT IN ANY SUCH EFFORT, GIVEN THE MAGNITUDE AND ADVANCED STATE OF UNITED STATES BIODEFENSE ACTIVITY AND THE BIOTECH INDUSTRY IN THE UNITED STATES.

WHAT WE HAVE SOUGHT IS A BALANCE THAT WOULD ACHIEVE GREATER BENEFIT IN THE NON-PROLIFERATION AND ARMS CONTROL OBJECTIVES THAN COSTS TO LEGITIMATE NATIONAL SECURITY AND COMMERCIAL INTERESTS. THAT IS A JUDGMENT THAT WILL BE MADE AT SENIOR POLITICAL LEVELS OF THE EXECUTIVE BRANCH, INFORMED BY BOTH THE SUBSTANTIVE ANALYSIS OF THE REVIEW I CHAIRED THIS SPRING AND THE POLITICAL CONTEXT OF THE NEGOTIATIONS.

SEVERAL COUNTRIES HAVE STATED THAT THE NEGOTIATIONS MUST BE COMPLETED BEFORE THE BIOLOGICAL WEAPONS CONVENTION FIFTH REVIEW CONFERENCE THIS NOVEMBER. THE UNITED STATES DOES NOT AGREE. WE HAVE ALWAYS TREATED THE NOVEMBER REVIEW CONFERENCE AS A TARGET, NOT AS A DEADLINE. THIS DOES NOT MEAN WE ARE BLIND TO THE VERY REAL POLITICAL IMPLICATIONS OF NOT FINISHING THE PROTOCOL'S NEGOTIATIONS BY THE CONVENTION'S REVIEW CONFERENCE. THE PERCEIVED NEED TO SEARCH FOR A FORMAL WAY TO STRENGTHEN THE BIOLOGICAL WEAPONS CONVENTION ORIGINATED IN THE FRUSTRATION OF THE THIRD REVIEW CONFERENCE TO FIND OTHER WAYS TO ENHANCE IMPLEMENTATION OF THE CONVENTION. MANY OF THE ISSUES THAT HAVE CONSUMED THE BULK OF NEGOTIATING TIME IN THE AD HOC GROUP RELATE DIRECTLY TO CONCERNS ONE OR MORE COUNTRIES HAVE EXPRESSED IN PREVIOUS REVIEW CONFERENCES OF THE CONVENTION. CONTENTIOUS ARGUMENTS HAVE BEEN DIVERTED FROM THE FOURTH REVIEW CONFERENCE TO THE AD HOC GROUP. IF THERE IS NO SENSE DURING THE FIFTH REVIEW CONFERENCE IN NOVEMBER THAT A PROTOCOL ADDRESSING THESE ISSUES IS IN SIGHT, WE CAN EXPECT A VERY TROUBLESOME REVIEW CONFERENCE, WITH SOME BITTERLY FOUGHT ATTEMPTS TO INCORPORATE NATIONAL VIEWS IN THE FINAL DOCUMENT OF THE REVIEW CONFERENCE. THIS IS ANOTHER FACTOR THE UNITED STATES WILL TAKE INTO CONSIDERATION IN ITS APPROACH TO THE PROTOCOL.

MANY IMPORTANT AND CONTENTIONS ISSUES STILL REMAIN TO BE SOLVED IN THE PROTOCOL NEGOTIATIONS. AMONG THEM, ONE ISSUE CONTINUES TO BE A LIGHTNING ROD FOR DISPARATE VIEWS OF THE UNDERLYING PURPOSE OF THE NEGOTIATIONS THEMSELVES. THAT IS THE ISSUE OF EXPORT CONTROLS. I HAVE PRESENTED THE UNITED STATES VIEW OF THIS ISSUE BEFORE - BUT I WOULD LIKE TO REPRISE IT BRIEFLY. THE UNITED STATES DOES NOT VIEW NEGOTIATIONS ABOUT A PROTOCOL TO THE BIOLOGICAL WEAPONS CONVENTION TO BE A DISCUSSION OF TRADE ACCESS. IT IS A NEGOTIATION ABOUT NATIONAL SECURITY AND CONFIDENCE IN ATTEMPTS TO CONTROL AND ELIMINATE A PARTICULAR WEAPON OF MASS DESTRUCTION - BIOLOGICAL WEAPONS. WE ARE NOT PREPARED TO UNDERMINE, WEAKEN, OR OTHERWISE COMPROMISE OUR OVERALL

APPROACH TO COUNTERING PROLIFERATION OF BIOLOGICAL WEAPONS CAPABILITY THROUGH ANY PROTOCOL. THE UNITED STATES BELIEVES THAT ALL THE TOOLS CURRENTLY AVAILABLE TO REDUCE THIS THREAT, AS WELL AS ANY THAT WE WOULD BE PREPARED TO ACCEPT IN A PROTOCOL, ARE COMPLEMENTARY. WHILE NONE ALONE MAY BE A SUFFICIENT ANSWER TO THE THREAT, NONE SHOULD BE DISCARDED OR WEAKENED - IT IS A PRICE MUCH TOO DEAR TO PAY FOR ANY MULTILATERAL REGIME.

IT IS A TIME FOR DECISION IN THE AD HOC GROUP NEGOTIATIONS. CHAIRMAN TIBOR TOTH USED HIS CONSIDERABLE SKILL AND IMAGINATION TO PRESENT A POTENTIAL WAY FORWARD IN THE NEGOTIATIONS. THERE ARE LEGITIMATE QUESTIONS, STILL UNANSWERED, WHETHER THIS EFFORT IS ADEQUATE. IF THE ANSWER TO THAT QUESTION IS "NO," THERE IS THE FOLLOW-ON QUESTION ABOUT WHAT SHOULD BE THE ALTERNATIVE. THE UNITED STATES IS GRAPPLING WITH THOSE QUESTIONS, AND I WOULD END ON A REPETITION OF A POINT I MADE EARLIER: WE UNDERSTAND THE OBJECTIVE, AND WE UNDERSTAND THE BALANCING WE MUST DO IN EVALUATING THE AVAILABLE OPTIONS. THE UNITED STATES INTENDS TO MAKE THOSE DECISIONS IN THE LIGHT OF INTERNATIONAL SECURITY AND THE WELFARE OF ALL COUNTRIES IN DIMINISHING THE THREAT OF BIOLOGICAL WEAPONS.

Mr. TIERNEY. Thank you. Is there some indication that the Ambassadors will be with us soon so they can testify before the committee?

Mr. SHAYS. Yes, they asked for a postponement until the administration is totally certain in what direction they want to head and they feel that will happen in the next few weeks. And let me say to the gentleman, we will call them before the committee.

Mr. TIERNEY. Thank you. My concern is of course this will be at least the third instance of when this administration has unilaterally pulled back from an international commitment that people in other countries thought they had some right to rely would at least be consulted and have the issue discussed with them before such action was taken. You have the Kyoto Accords and the national missile defense situation and now this. I would like to see us have a more cooperative attitude and relationship with people in dealing with an international respect for our own credibility and for the sake of trying to move forward on some of these.

I get the sense, Mr. Zelicoff, that you don't feel that any protocol is useful in this or am I overstating the case?

Mr. ZELICOFF. Yes, I'm sorry you weren't here earlier. You are overstating the case. I do believe that a protocol that focuses on challenge inspections for specific cause as opposed to routine random inspections for no cause at all.

Mr. SHAYS. Could I ask you to defer? Don't be offended by someone. A Member is in many places and I don't want to discourage a Member from asking any question if they weren't here. I just want to say to all the panelists this gentleman works very hard and he may ask a question and we'll just repeat it. And frankly it takes me three times to understand it, so it is good reinforcement for me.

Mr. ZELICOFF. Thank you. And the second item, Mr. Tierney, was enhanced disease surveillance, and I believe that would make a very credible protocol.

Mr. TIERNEY. As that was just discussed—while you are saying that, I have the same thought the chairman had and that is sort of after the horse is out of barn and a little bit tough in doing as much good collectively in that. Going back to your first issue, how do—is the only way I'm going to know to challenge it—how am I going to make a challenge if I don't have any information from inspections or other activities?

Mr. ZELICOFF. Through the usual means, which tend to be national technical means or some sort of evidence that an accident has taken place. It is a tough problem.

Mr. TIERNEY. Again, a situation would have to occur, an accident or something like that, to give us an indication.

Mr. ZELICOFF. I wouldn't rule out the possibility of intelligence identifying a site that is high probability for violation.

Mr. TIERNEY. Dr. Smithson, do you agree? Is that your position also? Do you have other reasons or other ways that you think we might move forward on this?

Ms. SMITHSON. The groups of experts that sat around the Stimson Center's table from industry, from research institutes, from academia, from defense contractors and also veterans from various types of inspection activities would all advise that this

chairman's text be rejected simply because it's not strong enough to do what we would like for it to do. However, they would also ask that the U.S. Government and U.S. industry go forward with rigorous field trials and additional technical research to ascertain what can be done. And two of those groups, those from academia and from industry, strongly believe, in fact laid out their monitoring strategies for how inspectors could differentiate between legitimate facilities and those that might be cheating and to do this on a reliable basis.

Mr. TIERNEY. Would they rely on inspections for this?

Ms. SMITHSON. Absolutely.

Mr. TIERNEY. Would it just be inspections for cause or interim inspections, periodic inspections?

Ms. SMITHSON. It would be both types, challenge inspections if cause were demonstrated or if intelligence indicated there were cheating taking place as well as a more routine type of inspection. In fact, the defense contractors, academics and the industry groups all did not want this to rely solely on challenge inspections. They believe that routine inspections are needed.

Mr. TIERNEY. For your own personal opinion on that, is there any way that this protocol could be saved if we extended out the date beyond November? Is it something that could be worked with and have a result that was more in line with things that would be acceptable for the group she talked about?

Ms. SMITHSON. If I had a nickel for every time I heard someone say if we don't seize this window of opportunity all chance will be lost and we will lose the agreement, well, I would be a very wealthy woman. I don't believe that we need to hurry this thing and get it done by November. I would rather have us get it right than get it fast. And unfortunately, to do so will take more time and effort on the part of the U.S. Government and U.S. industry so, yes, this can be salvaged but not necessarily with the formulas that are currently on the table or the technologies that are currently being discussed.

Mr. TIERNEY. Dr. Rosenberg, what do you feel about postponement versus moving forward with what is on the table now?

Ms. ROSENBERG. I would like to see the negotiations continue, but what I would like isn't the point.

Mr. TIERNEY. No, but it is interesting and it helps.

Ms. ROSENBERG. I am familiar with the negotiators. I spend a lot of time over there and I know our allies are fed up with the whole process. They feel that they have been foiled at every turn by the United States. They have tried to make a strong protocol. The United States has insisted on weakening it. Now the United States says it is too weak. They just don't see any point in continuing this charade. So whether it is going to be possible to continue I have very strong doubts at this stage, and that is why I think we should take what we can get now if possible.

I also want to comment on what Dr. Zelicoff said, at least if I understood him correctly, that a good protocol would be one that would concentrate on challenge inspections. I know this is widespread thinking in the government right now. I want to point out that challenge inspections are a very political mechanism, that there have been no challenge inspections under the chemical weap-

ons inspections that has been enforced over some years and there is thought that maybe there never will be because the longer it is put off, it's also likely the more fear there is to bring a challenge.

Second, there is also a mechanism for investigation of an alleged use of biological weapons. Under the United Nations there is a general resolution that gives the Secretary General the power to assemble experts and investigate a possible allegation. If it is not done that way, the only better way is to have a standing inspector and you can't have a standing inspector to do challenge inspections that doesn't do anything else. They would soon lose their expertise because they are going to happen once in 10 years, if ever. Therefore, for that reason alone you have to have what Amy called routine, but which is really a dirty word in negotiations. Never call biological weapons inspections routine. They are random inspections but not routine.

Mr. TIERNEY. Could you just expand a little bit on what some of the demands that the United States made were that weakened this to the point where now it is in a difficult situation?

Ms. ROSENBERG. Well, one of them was the trigger, the criteria for declaring defense facilities. Our allies would have liked to have had all defense facilities declared, just at least they exist. But the United States objected to that. The chairman's text therefore requires only declaration of a certain kind of defense facilities and only those that have more than 15 full-time employees. There are a lot of outputs built into the chairman's text at the insistence of the United States. I still think that the chairman's text concentrates on the most important sites, but it leaves out others that I think should be declared, and I don't see any way in which that is going to happen in the foreseeable future.

Mr. TIERNEY. Are there others?

Ms. ROSENBERG. There are other aspects, too. Our allies the British, who have been the prime movers here as friends of the Chair on compliance measures, have wanted a declaration of production facilities. The United States was pretty much going along with that until just the last couple of months in which we pulled our support of that. And that is what has left vaccine facilities hanging out there. As Dr. Woollett pointed out, they are being singled out. We would agree with PhRMS that it would be much better to have to require declaration of all the production facilities, including vaccine, without singling them out as some special case and of course have this kind of declaration be a broad but shallow declaration which at least covers all the kinds of facilities without delving too deeply into their possibly confidential information. We would support that. But the question is what about other parties. The chairman has tried to make a compromise text that he can sell to everyone. There is the problem.

Mr. TIERNEY. Thank you. Dr. Woollett, is this the type of a protocol that we should enter into now and then look for a second round of negotiations?

Ms. WOOLLETT. No, I don't believe it is. I think there is an undue focus on capability and we shouldn't question at all the vast majority of the worldwide capability in pharmaceutical and biotechnology is in the United States. And we don't believe that legitimate capability should be put on trial, particularly when we are having dis-

cussions along the lines of the experiences in Iraq. We knew they were up to something. Our facilities are undoubtedly the most capable in the world. If someone was going to accuse us of being up to something, there is no way we can overcome the lack of a presumption of innocence and prove to somebody so inclined that we weren't up to something. And I think this is why we are adverse to any form of nonchallenge inspection. We don't know what we have got to show in order to be off the hook. We can show what we do, but apparently that is not enough if somebody thinks there is something wrong in what they see in our facility, and this is the quandary we face. How do we avoid the false positives of any such inspection, and how do we avoid them slipping in some allegation that compromises that facility's ability to make life-saving medicines and those patients' confidence in those medicines that they are taking to keep them alive?

Mr. TIERNEY. Colonel, do you want to make a comment on this?

Colonel KADLEC. Sir, I have to put myself in the camp that believes it is better to get it right than something that is not right and basically may in the long term undermine what the original treaty was trying to do. I mentioned earlier that it was by no accident that the original drafters of convention could not put together verification measures, not because they did not want to but because it's hard. I am suggesting it is not any easier today. And clearly Dr. Rosenberg pointed out that there are certain exemptions and it clearly puts out the possibility that the proliferator would have a road map to, if you will, circumvent the measure of a protocol to pursue a biological weapons program.

The other thing I would like to point out, and it gets back to the routine side of the house, which is we have a very capable military today and we don't go to war every day. We don't have routine wars, thank God. It would seem odd to me to say that we have to have routine inspections to maintain the proficiency of the inspectors. It seems like exercises could be done to maintain their proficiency, particularly in the realm of challenge inspections where it really does require a very expert cadre of people to look at it, look at a circumstance. So I would kind of suggest that routine again because of—to have routine inspections just because we need to train inspectors doesn't make sense, particularly as it was pointed out earlier that their likelihood of detecting or even deterring someone's prohibited activities is probably very low.

The last point I would like to make and, again to capture something mentioned earlier, it goes back to—I think Dr. Smithson mentioned that you know it when you see it when you walk into a facility. I have had that experience on several occasions, certainly at Al Hakam in Iraq, and a couple of other places there. But one of the ones where I had a similar one was a large production facility that had an earthen covered bunker, that had high security, that had an explosive handling facility, that had within its culture collection pathogens of concern and also had special handling of waste, all what I would call certainly indicators of suspicious activity.

But that facility wasn't in Iraq. It wasn't in Russia. It happened to be in Michigan. And clearly from my experience on the ground, there is a pretext probability here. I always kind of joke around

with the idea that people are not ghost chasers because they don't believe in ghosts. It is because they believe in them. Certainly in these dual use facilities you can find yourself in a situation because of in this case where historically the production facility occupied an area that was formerly a state police facility and had all these unusual features about it, just because that is what was made available to them back in the 1950's. So I am cautious to sign up to the camp that says, well, we can tell it completely and it clearly gets back to this issue of intent that is extremely difficult.

And I would like to maybe comment on a comment that Dr. Zelicoff made, which suggests that national technical means may be the way at this problem. I would suggest it is probably human intelligence because you do hope, as the chairman has said, a whistleblower or maybe an informer inside can provide you that kind of information that gives you the probability that facility or activity is certainly doing something nefarious.

Mr. TIERNEY. Isn't that more likely to happen if you have some sort of regularized inspections as opposed to just challenge inspections?

Colonel KADLEC. Well, sir, and again I will not use the Iraqi experience but certainly my experience in the department trial visits I participated in, that the facilities that we went to did an inordinate amount of preparation, both physical and, if you will, personnel preparation. So I doubt, and this was just for a routine visit, this was not for a challenge scenario. This was at a facility that was doing all legitimate work. So I can't help but believe that if a proliferator has a facility that would come up for a routine inspection, that they would probably go through a similar preparation phase that would probably involve more than just simple preparation, but active denial and deception methods that I think would if not fluster, confuse even the most experienced inspector.

Mr. TIERNEY. On the whistleblower aspect of it, a whistleblower is going to need an opportunity to talk to somebody that they are not going to necessarily get if it is just on a challenge basis, but if it was on a periodic inspection basis then the opportunity that otherwise wouldn't exist it would be there.

Colonel KADLEC. Well, that would be his first and last time to blow that whistle. I can guarantee you, as experienced in Iraq in the cases where an individual or others have kind of raised their hand and said something is wrong there, they haven't been seen again.

Mr. TIERNEY. I think I understand pretty much what the issues are on that, but I would like to give Dr. Rosenberg a last crack at this to respond to anything you might have heard that you think you can enlighten us on.

Ms. ROSENBERG. On that question of whistleblowers, actually you don't have to have a whistleblower. In a random visit there will be interviewing of various workers in a facility, and one of the important—in fact a very important tool used by UNSCOM in Iraq was interviews in which they were able to pick up inconsistencies between things that different people said. This is the kind of thing you don't get a chance to do unless you have some kind of random type visit. What else can I say?

Mr. TIERNEY. What do you say about the false positive argument? I get the feeling that you might be inclined—and correct me if I'm putting words in your mouth—you might be inclined to say go with what we have here and then if we can improve it, improve it later. Do you see harm coming from what is being proposed now and as part of that harm this concept that it might be a false positive?

Ms. ROSENBERG. I think when you get 143 countries together to set up a regime that they are all going to be subject to the chances of its being dangerous for any of them are vanishingly small. There are going to be false positives that will end up as accusations for some country, maybe the Netherlands let's say, is just not a credible argument. The problem is to have tight enough measures to get anything at all, when you are trying to get a consensus agreement on a treaty with all of these countries involved. So I think it is a red herring, the false positive.

Mr. TIERNEY. You think that the document, at least as I understand it to be at this point in time, does not create that kind of a concern?

Ms. ROSENBERG. It has very strong restrictions on when you can actually go in to do a challenge. There has to be a vote by the executive council and the most—the easiest vote is a 50 percent vote of those present and voting saying that the inspection can take place. That would be for any facility inspection would have to go through that.

My group has done a study on looking at past votes in the Security Council and the General Assembly and so on and what the different blocs would do and we determined that a 50 percent vote of this type would essentially never end up with any challenge inspection in the United States. It is impossible given the allies that we have. So it is—we opted for that as the best possible formula because it will allow inspections in the places that we might be concerned about but will not subject our industry or others to inspections that are really not meaningful or don't have a basis that's significant.

Mr. TIERNEY. Thank you. I was intending to give you last word, but at the expense of Mr. Zelicoff not passing the cardiogram he was talking about earlier, I would let him to speak up.

Mr. ZELICOFF. I did pass the poly—the cardiogram. Did you, sir, is the question.

Dr. Rosenberg can assert whatever she wishes, of course, but the science does not support her. In her last statement she slipped from talking about routine inspections into challenge inspections and the issue about false positives is not with regard to challenge inspections. In fact our national trial experience shows that with the properly phrased challenge inspection the probability of a false positive is routinely small. It is rather during routine inspections that false positives are a problem, and indeed in all of the U.S. national trial inspections a false positive was generated, which is to say two things: The team was either unable to convince itself that no illicit activity was taking place or if there were perfectly legitimate activities taking place the inconsistencies that normally occur in interviewing people who work at any site raise ambiguities.

So it was interesting in the lessons learned in the U.S. national trial inspection experience, which I would be happy to submit for the record, what we learned from the people at each of these facilities, and these were disparate facilities, separated both in time and space, had nothing to do with each other. What we learned from each of the facilities was were a routine inspection to take place under the Biological Weapons Convention, they would send their staff members home and they would have a rehearsed set of statements to make delivered by one or at most a few administrators to avoid the ambiguities that took place, and that would be a perfectly legitimate response on the part of the facility.

So in the routine inspections, as distinct from challenge inspections, the probability of a false positive, while Dr. Rosenberg may assert it is a red herring, in our national trial experience was almost a certainty.

Mr. TIERNEY. Do you want to leave it at that, Doctor?

Ms. ROSENBERG. No, I won't leave it at that because I suspect that he didn't carry out his little trial according to the rules in the chairman's text at present, which gives all access to the discretion of the host government during a visit and prohibits the inspectors even from mentioning whether or not they were turned down for requested access in a visit. So there is hardly any way that I can imagine that any false allegations could come out of such a visit.

Mr. TIERNEY. Well, thank you all very, very much.

Mr. SHAYS. We will get the responses to this. This disagreement among panelist keeps us awake, so I thank you.

I would like to ask unanimous consent that the following article from the Chemical Weapons Convention Bulletin, Issue No. 39, March 1998, provided by Professor Matthew Meselson, co-director of the Harvard-Sussex Program on Chemical and Biological Weapons, Armament and Arms Limitation, be included in the record. And this is at the request of the minority. I think we had asked him and he couldn't make it. So we will do that without objection.

I ask further unanimous consent to include in the record a letter to the subcommittee received from the Centers of Disease Control on the subject of global disease surveillance and the BWC. Thanks.

[The information referred to follows:]

Jun-01-01 15:22 From-EXECUTIVE SECRETARIAT T-300 P.02/04 F-731

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUN 1 2001

The Honorable Christopher Shays
Chairman
Committee on Government Reform
Subcommittee on National Security, Veterans Affairs,
and International Relat ıs
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Shays:

Secretary Thompson has asked me to thank you for your recent letter regarding the Subcommittee's review of international efforts to develop a compliance protocol for the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction* (*BWC*), and to respond directly to you.

As requested in your letter, the Centers for Disease Control and Prevention (CDC) is providing the following information:

1. A detailed description of the extent of involvement by the Centers for Disease Control and Prevention (CDC) in the development of the BWC Protocol.

   Response:

   CDC has had no official involvement in the development of the *BWC* protocol. Since 1996, and at the request of the negotiating team, Dr. Stephen M. Ostroff, Associate Director for Epidemiologic Science, National Center for Infectious Diseases (NCID), CDC, has informally reviewed sections of the rolling text that addresses outbreak investigations.

2. A specific account of CDC representation at US interagency discussions on the protocol and at the negotiating sessions in Geneva Switzerland, including names and dates of participation.

   Response:

   CDC has been neither officially represented at the U.S. interagency discussions on the protocol, nor at the negotiating sessions in Geneva. Dr. Ostroff participated on several occasions in meetings of the interagency working group on the *BWC*. This involvement

began with a tabletop exercise (August 27-30, 1996--Defense Special Weapons Agency Unusual Disease Outbreak Exercise) held by a DoD contractor to demonstrate to and inform treaty negotiators about the epidemiologic investigation of unusual disease outbreaks. Dr. Ostroff and Dr. Joseph McDade, Deputy Director, NCID, were on the panel, as was a CDC Epidemic Intelligence Officer. As a result of this meeting, Dr. Ostroff met the principal U.S. negotiators, including Ambassador Mahley, Mr. Ken Ward (both in the Arms Control and Disarmament Agency, [ACDA]), Mr. Bob Kadlec, and Ms. Martha Girdany. Dr. Ostroff subsequently attended at least one and possibly two meetings of the interagency working group at ACDA while in Washington for other purposes.

Dr. Ostroff also attended a meeting for federal agencies on the *BWC* status called by Ms. Elisa Harris of the National Security Council, and a meeting with Ms. Harris, Mr. Ward, and representatives of the American Society for Microbiology (ASM), during which ASM was informed of the status of the treaty negotiations. Both meetings were held in Washington, D.C., and in these instances, Dr. Ostroff was in Washington for other purposes.

During May 12-13, 1998, several CDC staff; Dr. David Dennis, Chief, Bacterial Zoonoses Branch, Division of Vector-Borne Infectious Diseases, NCID; Dr. James LeDuc, Acting Director, Division of Viral and Rickettsial Diseases, NCID; and Dr. Steve Ostroff participated in a DOE workshop directly related to the *BWC* treaty negotiations, which was held at Lawrence Livermore National Laboratory, Livermore, California, to discuss disease investigation in a hostile environment. The workshop was co-sponsored by the Center for Non-proliferation Studies at the Monterey Institute of International Studies and the Center for Global Security Research at Lawrence Livermore National Laboratory. A copy of "Procedures for Investigating Suspicious Outbreaks of Infectious Disease in a Noncooperative Environment;" edited by Jonathan B. Tucker; Proceedings of a workshop held in Livermore, California; May 12-13, 1998, is enclosed.

Dr. Ostroff participated in and spoke at a conference sponsored by the Dutch government in January 29-30, 2000, in The Hague where all the treaty negotiators were invited to discuss the composition and function of the agency, which would be set up to monitor the treaty.

Between 1992 and 1996 when Dr. James LeDuc was seconded to the World Health Organization (WHO) from CDC, he met most of the then U.S. delegation to the *BWC* and informally communicated with them on global infectious disease surveillance issues. In addition, during a special informal session, he gave presentations on global surveillance and possible relationships to the *BWC*, and once during a formal session. Both talks focused on the role of WHO in global surveillance and were presented as part of his duties as a medical officer at WHO rather than as a spokesperson for CDC.

3. Copies of all correspondence between CDC and the Departments of State and Defense, and any other US agency concerning methods designed to monitor implementation of the BWC.

Response:

CDC has no official correspondence between agency officials and the Department of State, the Department of Defense, or any other U.S. agency concerning methods designed to monitor implementation of the *BWC*.

4. Correspondence with international organizations such as the World Health Organization related to the protocol.

Response:

CDC has no official correspondence between agency officials and WHO, or other international organizations regarding the protocol.

I hope this information is helpful.

Sincerely,

Jeffrey P. Koplan

Jeffrey P. Koplan, M.D., M.P.H.
Director

Enclosure

Mr. SHAYS. Did you want to make a comment? We are going to have some disagreement and I just want to make clear what the disagreement is, not that we will solve the disagreement.

Mr. ZELICOFF. I simply want to state our little trial inspections, as Dr. Rosenberg pejoratively referred to them——

Mr. SHAYS. You're getting kind of uppity. You've got to loosen up here.

Mr. ZELICOFF. I get uppity when the truth of science is demeaned.

Mr. SHAYS. I know, but then she gets uppity and I get uppity and we all get uppity.

Mr. ZELICOFF. Well, science is what science is and in the case of our little trial inspections, they occurred over 5 days involving 30 inspectors as well as dozens of people at facilities, and I think it discounts the efforts of all of the interagency participants to characterize them as little, insignificant. These are by far the most extensive trial inspections that have ever been done. Thank you.

Mr. SHAYS. Thank you. I would like to know what is the extent of the disease monitoring vision under the Chairman's Text. Anybody want to jump in?

Ms. ROSENBERG. Yes, can I say something about that? That section of the Chairman's Text comes directly from the rolling text and it is totally unbracketed; that is to say, it has been totally agreed upon by the negotiators.

Mr. SHAYS. Define rolling text.

Ms. ROSENBERG. It is the draft text which keeps getting updated. So at some point the draft text was taken which the chairman—and he tried to resolve all of the unresolved parts of it, but he didn't have to do anything with that section because it was already fully agreed. And the whole section on cooperative scientific and technological activities is focused on infectious activities, on surveillance, diagnosis, recognition, control, prophylaxis, and so on of infectious diseases. It sort of repeats itself over and over about supporting and promoting all of these activities. And the interesting thing is that not only does it say that countries should promote, that the parties of the treaty should promote these activities, but they have to declare annually what they have done to promote them, and there will be a cooperation committee that will read these annual declarations and be empowered to make comments or suggestions.

Mr. SHAYS. I need a translation. The bottom line is, is there extensive monitoring in surveillance in the rolling text or are we basically ignoring this issue? And I open that up to you and then to others.

Ms. ROSENBERG. Well, the first point I think I should make is to clarify, the treaty itself is not proposing to monitor diseases and that no treaty should try to do that because infectious disease——

Mr. SHAYS. Am I mixing the word "monitor" and "surveillance"?

Ms. ROSENBERG. No, I don't mean to make that distinction. I am saying it shouldn't be done under an arms treaty. I am saying it is a public health issue. If you try to carry out a public health measure under an arms treaty you will not find cooperation from all the groups and governments that you need it from.

Mr. SHAYS. Let me respond to that. Whether or not you find cooperation, the issue is, is that necessary and helpful to have a good treaty?

Ms. ROSENBERG. It is very important and that is why the treaty has this section which calls upon its parties to do something on these problems and to report on what they have done. But the activities will not be carried out directly under the treaty organization, but will be left to the parties to work with the international organizations outside the treaty, but to meet the ends that are specified under the treaty, and I think everybody in the field recognizes that this is the only way to handle this if you want to get public health cooperation.

That is why the World Health Organization and others have gotten together to make a proposal about how to carry out those goals that are specified in the treaty, and the parties who are negotiating have found—have welcomed this——

Mr. SHAYS. Are you making an assumption that others would agree with? And then am I hearing you correctly? Are you saying that to make it part of the treaty means that information of health statistics will be less readily available?

Ms. ROSENBERG. Oh, absolutely. The World Health Organization is always willing to make information like that available.

Mr. SHAYS. No. Listen to my question. What I was hearing you say, and I want to just make sure I heard you properly, was that the reason health information, health surveillance is not part of a treaty is that it might distort the type of information you get——

Ms. ROSENBERG. Yes.

Mr. SHAYS [continuing]. On health statistics, and so I hear you saying health statistics. You don't want to bring it into a treaty because you want accurate health statistics. Are you saying that?

Ms. ROSENBERG. Right.

Mr. SHAYS. Are you saying that?

Ms. ROSENBERG. I am saying that. Because you have to remember that when there is a serious outbreak in a country, it cuts off tourism, trade. India had a big problem when it had the plague break out a few years ago. It lost—millions of dollars in economic loss. So countries are not—especially if it might suggest that they perhaps violated an arms treaty. Perhaps there is an epidemic that somebody might think was due to a biological weapon.

Mr. SHAYS. But, Doctor, what you are reinforcing in my own bias, and I admit it's a bias, there are all these reasons why we can't write a treaty that will really do the job. That's kind of where I am coming from. And I didn't start out that way. And you're making an argument that you can't—if you really want a treaty that works, it would strike me—and I realize, you know, and I acknowledge, you know, that something is out of the barn, but, still, that is going to be one basis for knowing if we have got a gigantic problem. You know, we see a distortion in health in a certain area, and we try to assess it, and we come to some conclusions. It's natural or not natural. But we want that information.

Let me ask you this. First, let me let others comment to what you said, and then I'll ask the next question. Yes, Dr. Woollett.

Ms. WOOLLETT. It's an interesting parallel to transparency. We want people to be transparent. And what I'm noticing in what

you've said is de facto is part of an arms control treaty, you're dissuading them, because it is in a context that has a certain supposition to it. And I think that's where the U.S. pharmaceutical biotech industry has a problem, because routine inspections become part of us being somehow checked up on for what we shouldn't be doing, rather than us affirmatively showing what we are doing, which is the true meaning of transparency. So there is actually a parallel in the surveillance side. The disease surveillance indeed should be done. We are not adverse to the world knowing what we do, but in the context of arms control, there is a context that can be very difficult to overcome.

Mr. SHAYS. Any other comment, and then I'll——

Ms. ROSENBERG. So the advantage of the protocol is that it requires this to be done, but it doesn't actually do it. It allows countries to do it outside and then report on what they've done. That's why an organization like the World Health Organization is essential to carry out something like this, because it's the only health organization that every country feels they have some part in, they are members of and they can trust it to have their interests at heart.

Mr. SHAYS. Dr. Woollett, do you want to make—anybody maybe a comment? Yes.

Colonel KADLEC. Sir, I would like to, because it kind of gets back to maybe a point I made earlier but also I think is consistent with the theme here with regard to this protocol, that some of the more significant measures to strengthen, if you will, our ability to either detect or respond to these events, a possible event of use or even development, are going to exist outside the protocol and that they deal with global disease monitoring that is outside, if you will, the text of the protocol but certainly a very important supplement part, if not a foundation piece, to build a protocol on.

And the same thing with intelligence. I mean, that's, again, one of these kind of just odd kind of situations. And, again, it runs counter to maybe some of the other experiences in some of the more conventional elements of arms control to date that you do look for more ancillary, outside the formal text kind of capabilities to help you pursue nonproliferation.

Mr. SHAYS. That would argue, though, for not having to make a challenge, because they're not part of the protocol, so you couldn't count it as a challenge. That would argue for just being able to do it at will based on all of this ancillary information that you get. In a sense, it's a challenge, but you can't use it as a challenge.

Am I speaking in tongues here?

Colonel KADLEC. Well, no, sir. I think the point I would like to make is that outside information is what helps you go to a challenge scenario.

Mr. SHAYS. I know, but it's—we're hearing one point, is that you don't need a challenge, and you shouldn't operate based on a challenge. And the other argument is there should be probable cause. Now, if it's not a part of the treaty—let's just deal with this issue of probable cause. If it's not part of the treaty, this ancillary information, could you use it as a probable cause? And it would strike me you can't, because it's not part of the treaty process. And maybe that's an assumption I'm making that's incorrect.

Colonel KADLEC. I would suggest otherwise.

Ms. WOOLLETT. Yeah. My understanding is that any evidence that you have that you're willing to declare is a basis for the due process, a bona fide allegation you can indeed use.

Now, of course, in declaring it, there may be other concomitant liabilities to where you got it from, but the basis of knowing that there is a reason to go for a challenge, putting the evidence on the table and going ahead with the challenge, you're not limited at all to where you got the information from.

Mr. SHAYS. You raised the question of capability and—and versus intent. Tell me, the United States potentially has what world's capability? Is it 40 percent, 50?

Ms. WOOLLETT. It's into the 90's, depending on where you do the cutoff in terms of sophistication. But of the most—I mean, for instance, if we look at pharmaceutical R&D anticipated for this year by our companies alone, something like $30 billion is the total expense, of which the high 20's are in the United States. The vast majority of the most sophisticated capability unquestionably is in this country.

Mr. SHAYS. With the gross domestic product of Europe being larger than the United States, I mean, the whole union, you're saying that our capability would dwarf Europe's?

Ms. WOOLLETT. In terms of R&D and where the pharmaceutical and biotechnological industries are doing their investments. Now, the three principal markets are Europe, United States, and Japan.

Mr. SHAYS. OK. But then let me—so should—is R&D more important than production in terms of——

Ms. WOOLLETT. Well, it depends where the cutoff comes. R&D is critically important in terms of confidential business information. That's your future products. Production is the high volume end, if that's where you do the cutoff in terms of the largest amount of——

Mr. SHAYS. OK. Let's just do production. Is production 50/50? I mean——

Ms. WOOLLETT. I would have to double-check. It's still the majority is the United States, but——

Mr. SHAYS. But with the rest of the world, then, we still are 50 percent plus?

Ms. WOOLLETT. I would say that Europe, United States, and Japan have the vast majority.

Mr. SHAYS. Take—so is Europe equal to the United States? And the reason is——

Ms. WOOLLETT. Not equal, but it's going to be high, too. It would be targeted, but—certainly on terms of vaccine manufacturer, there's four principal companies, two in the United States, one in France and one in Belgium.

Mr. SHAYS. Dr. Rosenberg, my visits, obviously, have been guided by the previous administration, but either administration—so I've met with some of our allies, and I have not heard the—and I'm sure it exists. So it's—the point you made about our allies' feeling that we've been dragging our feet in saying we're weakening the protocol and then we criticize it for being so weak, I know there's some who feel that way, but it's not your testimony that all our allies feel that way? I mean, there is——

Ms. ROSENBERG. Oh, yes. I can testify that they all do.

Mr. SHAYS. OK.

Ms. ROSENBERG. I——

Mr. SHAYS. You leave no one out? Australia you put in there?

Ms. ROSENBERG. I would—oh, no. They are definitely in there. Yes. Australia, Canada, New Zealand, all of Europe, the EUs, the strongest group.

Mr. SHAYS. And it would be your testimony before this committee that they feel the United States has consistently over the past few years weakened the protocol?

Ms. ROSENBERG. Yes. You know, worse than U.S. demands for specific weakening points is the fact that the United States has not stood together with the rest of the western group, which means that the western group was perceived to be split by other countries such as China. We now stand with China, Libya, Iran, Cuba and Pakistan. Those are the five dissidents with the United States.

Mr. SHAYS. Yeah, but for different reasons.

Ms. ROSENBERG. Well, no, not for different reasons. For objecting to the protocol. Pretty much for the same reasons. And the problem is that if the western group had been together they could have pushed through certain points that would have made a stronger protocol, but because everyone saw that the United States was not with them, it was not possible to do that and other points of view carried the day in many cases. So the United States has weakened the protocol in a number of different ways.

Mr. SHAYS. If anyone wants to jump in, I just want to ask a few more questions. Is there any—yes?

Mr. ZELICOFF. I was a member of the U.S. delegation from 1992 through 1999. I sat in on every western group meeting, and there was not quite an unanimity of opinion, sans the United States, that we were the treaty busters. The Japanese have violent disagreements with the rest of the western group as well, and I think it goes largely to where pharmaceutical capabilities are located as well as advanced R&D.

Mr. TIERNEY. Dr. Rosenberg, where would you say most objection comes from, the commercial end or the national security end of things?

Ms. ROSENBERG. In the United States?

Mr. TIERNEY. Yes, ma'am.

Ms. ROSENBERG. National security, although they love to hide behind industry. We know that—I mean, the classical case was the negotiation of the Chemical Weapons Convention, where the industry was very pro-treaty, and the United States was still blaming some of its positions on industry, when industry was saying, oh, no, we disagree with you. We want these measures. They've continued to do that with the pharmaceutical industry, and I've been very happy whenever there's been any resistance on the part of industry. But I don't believe that's where the real problem lies.

Mr. TIERNEY. Thank you.

Mr. SHAYS. Dr. Rosenberg, you talked about our allies and where they stand. Who represents the greatest threat in terms of the production and use of biological agents?

Ms. ROSENBERG. Which countries? None of our allies.

Mr. SHAYS. None of our allies. Correct. So who are they?

Ms. ROSENBERG. Well, you know, there's the usual 10 or 12 that are always cited.

Mr. SHAYS. And why don't you cite them for me. Who——

Ms. ROSENBERG. Which of the countries are?

Mr. SHAYS. Yeah.

Ms. ROSENBERG. North Korea, Syria, China, Israel, maybe Libya. I'm not sure whether Libya is in there right now. Well, India and Pakistan have occasionally been mentioned. I think they're pretty uncertain. It's the usual suspects, in other words.

Mr. SHAYS. We've left out one or two.

Ms. ROSENBERG. Right.

Mr. SHAYS. But the bottom line to it is that they are all—the irony is that I don't think you fear the United States using——

Ms. ROSENBERG. Absolutely not.

Mr. SHAYS [continuing]. Biological—and I didn't mean it to sound facetious. You don't. The irony is that we're negotiating with—in the treaty with people that we know for a fact produce it, and some have used it, and it's wild to be in an environment where I hear them speak and—frankly, very sanctimoniously—and yet we know that they're, as we speak, are involved in the production of biological agents and believe they would use them.

So what I wrestle with, knowing what I know as a Member of Congress—and there is more that we could put on the table that we can't. I mean, there is more that we know that we could put on the table, but we can't—we are dealing with people who we know have the capability and the interest and potentially the inclination to use biological agents. Those are the groups that I'm most concerned with, and yet I'm wondering if we have the capability with a treaty to prevent them from debating it, you know, research, doing the production and so on, because I side on the equation that says it's not the gigantic plant, but it is—you could do it in trucks. You can move trucks. You can do it in tents.

So get me beyond that. If I can get beyond that, then I would be a lot more receptive to your eagerness to see this treaty move forward.

Ms. ROSENBERG. Well, first of all, it's interesting that many of these countries that are suspected are involved in the negotiations, and I think that's a big advantage, because they obviously don't want to admit their interest in biological weapons——

Mr. SHAYS. Could I——

Ms. ROSENBERG [continuing]. And they therefore are not going to block the treaty because——

Mr. SHAYS. But that to me is the hypocrisy of it all.

Ms. ROSENBERG. Hypocrisy, who cares, as long as we are able to get onsite or, you know, as long as we're——

Mr. SHAYS. What good does it do to get onsite if they move the truck, if they move the tents, if they shut down the—see, because my—this is sincerely asked. It's right—and it's maybe my ignorance, but I can see the capability—if you were trying to put out incredible amounts of this, you would build a big facility, and it would have a signature to it, and you would all know. But a country that simply has more interest in terrorist use, in production over years but low output but over time it adds up, they have the capability, and the treaty in my judgment would be a joke——

Ms. ROSENBERG. Well, you don't——

Mr. SHAYS [continuing]. For preventing those.

Ms. ROSENBERG. Excuse me. You don't add up biological weapons, because they don't—most of them don't have that long a shelf life.

Mr. SHAYS. That's true.

Ms. ROSENBERG. And to do any——

Mr. SHAYS. Other than something like anthrax.

Ms. ROSENBERG. Right.

Mr. SHAYS. Well, but—no. With all due respect, we——

Ms. ROSENBERG. Yes.

Mr. SHAYS [continuing]. Are having all our military have vaccines on that, so it's not a minimal concern. Anthrax seems to be the one that most have the biggest concern about.

But, at any rate, your point is, some are, some aren't——

Ms. ROSENBERG. Well, my point is that I think there has been a lot of hype about the terrorist possibilities of bathtub production and that kind of thing. I think that producing—that developing and producing biological weapons is not an easy task. You might be able to produce it in a boxcar, but you have to have tested it somewhere before. You've got to have a lot of knowledge about it. You have to know how to deliver it. You have to know that it's going to stay viable as an aerosol. There is an awful lot of information you need. It's not simple.

And, you know, Russia, which was a problem—I mean, the Soviet Union, had tens—dozens of tons of smallpox and other agents stockpiled. Those are the problems that we have—we want to know about, and we didn't. So——

Mr. SHAYS. Yeah. I——

Ms. ROSENBERG [continuing]. You know, the boxcar that hasn't bothered to do testing somewhere, that hasn't gone through a whole process of development, you know, is—it may be a little—has a little bit of danger involved, but it's minor compared to the big time.

Mr. SHAYS. OK. I will—I see some hands going up. Mr. Gilman is here, and I would call on him if he would like to be recognized.

But I do want to say to you, it may be only a few years that I've been involved, this committee and me in particular, in the whole issue of this protocol, but it has been years and years that I've been involved in the issue of terrorism. And I can't emphasize enough my concern. I believe there will be a biological, chemical or nuclear attack on the United States. I have no reluctance in saying it. It's not a question of if it will happen. It's a question of when and where and, obviously, the magnitude.

And, you know, this kind of treaty, in my judgment, will not stop any of the kind of concern that I particularly have. And—but it's not to say we shouldn't be trying to make a good treaty. I just have not yet in my own mind seen how I would—if I were President of the United States, whether it was Bill Clinton or Mr. Bush—since I said Bill Clinton, I should say George Bush—President Clinton, President Bush—I don't know what I would be directing my people.

Let me just let you all make some comments, and we're ready to kind of draw it to a conclusion here. But, yes?

Colonel KADLEC. Sir, I just wanted to capture the point that you made earlier, that it is one of the paradoxes of a potential protocol to a—a protocol to the BWC that if you comply with the protocol, it somehow confers legitimacy to you potentially as a proliferator and, again, may obviate some of the other things that we are using today, some of the other tools that we have in our toolbox in terms of multilateral export controls that help us put a cap on this or delay it.

The second issue is the issue of whether or not there has been, as Dr. Rosenberg put out, a reluctance on the basis of national security or the industry—the pharmaceutical industry and their resistance to a protocol. And I'd just point out that it's very hard to divide the two today because of the role of economics in our national security, but more significantly to the point you just made about when you look at the role of terrorism and domestic response, how much we rely upon the pharmaceutical industry to provide those products that we need to use to either defend or treat our populace, should something happen. And I just throw that word of caution out.

Mr. SHAYS. Any other comment?

Mr. ZELICOFF. We have a very bad problem with biological weapons, and it's certainly possible to take the biological weapons proliferation problem and make it worse. Dr. Rosenberg is correct when she states that it's necessary to test biological materials to see if they will work as weapons, but that depends on the scenario. But, more to the point, that testing has already been done. Stockpiling is no longer necessary, because the parameters for growing materials into pound or ton quantities are also very well known and can take place in a matter of a few days or a few weeks.

And then, finally, whenever you think you've got your hands around the biological weapons problem and think that things like onsite inspections, routine visits are going to solve the problem, always consider the case of smallpox. Here is an agent that spreads perfectly well from person to person. So all of the criteria that Dr. Rosenberg laid out earlier, such as large quantities, aerosolization, need to know whether it infects, none of those things obtain in the case of smallpox.

Were a country to desire to undertake a terrorist event with biological weapons, smallpox is arguably the way that they would do it, and the facility necessary to produce it would be an Erlenmeyer flask that looks something like this or certainly about that size. And you can create enough material to infect a dozen or two dozen people, and then they will do the chain of dispersal for you.

And so this is what the American Federation of Scientists is putting out. The technologies of the 1950's that required large fermentation vats have been supplanted by the modern tools of biotechnology and a recognition that we have infectious agents that undermine all of the tenets that are put down in the treaty as signatures or markers of something adverse taking place. None of that would obtain in the real world.

Thank you.

Mr. SHAYS. Thank you.

Yes, Dr. Woollett.

Ms. WOOLLETT. I would just like to comment that if there is the prevailing assumption, which seems to be fairly broadly held, that we have signatories to the existing Biological Weapons Convention who don't comply with it, are we actually expecting them to comply with the protocol either? What are the checks? Are there any checks? It seems to be a real leap of faith that if they don't play cricket on one treaty they certainly will on another.

Thank you.

Mr. SHAYS. I'm ready to close. I know, Mr. Gilman, that you have a deep interest in this issue, but you're kind of coming at the conclusion. I don't know if you want to say hello or good-bye or hello and ask your question.

Mr. GILMAN. Well, Mr. Chairman, I want to thank you for conducting what I consider to be a very important issue as we address all aspects of terrorism.

I just would like to question the panelists. Is there any central authority in our government that is reviewing the possibility of biological and chemical weapons? Who is in charge of this in our government? Is there any—we found in exploring terrorism that we had a great deal of—a proliferation of responsibilities, and there was really no central—good central issue, and the chairman that had been conducting hearings, I think we found some 40 different agencies that had responsibilities. What about the biological and chemical weapons' situation? Is there any central authority? I'm asking the entire panelists.

Mr. SHAYS. Four are smiling. One is putting his hand over his nose. And three are smiling, one is smirking. Which one do you want to pick?

Mr. GILMAN. I'll go right down the line, starting here with our Mr.——

Mr. SHAYS. Let me just say it is an interesting question for you all outside of—directly outside of government now to tell us who you think would be responding.

Mr. GILMAN. Mr. Zelicoff, do you want to respond?

Mr. ZELICOFF. Is your question with regard to who is developing policy or who responds in the case of an attack?

Mr. GILMAN. Who is in charge?

Mr. ZELICOFF. I am not the person to answer that question.

Mr. GILMAN. Implementation, is there anyone in our government in charge of this?

Mr. ZELICOFF. The last time I looked, there was a chart that had a whole bunch of agencies connected with various strings of higher—but I don't know who is in charge now.

Mr. GILMAN. Ms. Smithson.

Ms. SMITHSON. Volunteering has its risks. I'm not sure I'm volunteering here, but it's fairly new in the Bush administration, but I think it's accurate and traditional to say that the National Security Council would be in charge of policymaking here, Bob Joseph and Rich Falkenrath being the two individuals that have this portfolio principally at the NSC.

The Ambassador to the U.S. negotiations is Don Mahley. He works out of the State Department.

The intelligence community, the Department of Defense and the Commerce Department also have very important roles to play in

policy formulation here, as does the Department of Energy, because they have a number of assets and have had members on our delegation for quite some time.

So, in a certain sense, it's somewhat similar to the organization to address terrorist problems. There are a lot of agencies at the table here.

Mr. GILMAN. But would you say it would be important to have some central authority to produce overview of all of these problems?

Ms. SMITHSON. I'd always advocate having central authority in our government, but find as a student and observer of our government's policymaking process that the individual who has the title for having central authority sometimes doesn't necessarily find himself or herself able to fulfill that role, because everybody is grappling for power.

Mr. GILMAN. Thank you.

Dr. Rosenberg.

Ms. ROSENBERG. Well, this is not an area that I've specialized in, but I do read some of the literature on it, and I observe that all the experts outside of government have complained rather bitterly that the program is much too diffuse, there is no central authority, and there is a desperate need to do something about that if we are going to have a meaningful response to bio or chemical terrorism.

Mr. GILMAN. Thank you. Dr. Woollett.

Ms. WOOLLETT. I think it has been fairly conspicuous that there is no central authority. We within the industry have worked with whomever is available whenever they are available, but one very apparent deficit is those agencies with the most technical expertise are the very few that are absent. For us, that would be the U.S. Food and Drug Administration and also those players at USDA that have expertise in the infectious diseases. Even CDC hasn't been actually very conspicuous at all. So it's been sort of policy devoid of the science and the technical, which ultimately will be the limitations on this protocol.

Thank you.

Mr. GILMAN. Colonel Kadlec.

Colonel KADLEC. Sir, I don't think I have much more to add than what has been offered here today. I think clearly that it seems like the group senses that there doesn't seem to be a focal point for this issue.

Mr. GILMAN. And, Mr. Chairman, just one other question. If we were to have some administration of people come before us on this issue, what questions should we ask the administration witnesses about the U.S. position on the BWC protocol when they do appear before our subcommittee? Can anybody——

Mr. SHAYS. One or two choices. What would be the questions we should ask?

Mr. GILMAN. We'll start again right down the line. Mr. Zelicoff.

Mr. ZELICOFF. If you had just one or two questions, I think the questions that I would ask are, should we move ahead with the current protocol as it is, or should we try to negotiate something that might be either more effective or more responsive to the needs of the United States?

And, second, I would specifically ask whether or not the administration has a position on strengthening, either directly or indirectly, the limited capability worldwide for disease monitoring.

Mr. GILMAN. Dr. Smithson.

Thank you, Mr. Zelicoff.

Ms. SMITHSON. Actually, the questions you posed to this panel and the other witnesses I think were quite good ones. Perhaps I could add to that list. Given the widespread expectation that the Bush administration will reject the chairman's texts, what steps forward do they have to—in mind to keep this process going guard constructively? And, second to that list, how will they turn the sour relationship with industry into a constructive one that helps create workable, meaningful monitoring procedures for this treaty similar to the relationship that existed between the U.S. Government and the chemical industry for working on the Chemical Weapons Convention?

Mr. GILMAN. Thank you, Dr. Smithson.

Dr. Rosenberg.

Ms. ROSENBERG. In Geneva, the negotiations—the U.S. delegation has talked rather freely about its dislike of the present negotiating mandate and how they prefer a different one. I would find out what kind of a mandate exactly they would like to have and what kind of a treaty protocol might come out of such a mandate and how would they—how do they propose to keep our allies involved and participating in such an endeavor.

Mr. GILMAN. Thank you, Dr. Rosenberg.

Dr. Woollett.

Ms. WOOLLETT. I think something along the lines of how will this protocol help global security and then in particular, commensurate with its costs with the United States, it will be undoubtedly focused on the United States. If it's not this protocol, what are the options they see for proceeding with a time line? I think a time line is critical. Thank you.

Mr. GILMAN. Thank you, Dr. Woollett.

Colonel Kadlec.

Colonel KADLEC. Sir, I would just offer one, and that is specifically one that is I think touched on by your subcommittee today, and that is, has the deterrence value of a protocol—of this particular protocol—this particular draft protocol.

Mr. GILMAN. Thank you.

Thank you, Mr. Chairman. I want to thank our panelists.

Mr. SHAYS. I want to thank the gentleman for coming, because I'm happy he asked the questions he did.

Before we actually hit the gavel, is there any closing comment that any of you would like to make? We'd be happy to have that. Yes.

Ms. ROSENBERG. I just would like to encourage you to continue to pursue the question of surveillance for infectious diseases, although we didn't really get into it today. I think it's a terribly important issue from the point of view of biological weapons and public health in general.

Mr. SHAYS. The two times I've gone to Geneva I've met with the World Health Organization, because I happen to agree with you. I

fear the spread of disease in a way that I didn't a few years ago, both natural and man-made.

You all were five excellent witnesses. This was a fascinating panel, and I liked a bit of disagreement that you had, and I learned from all of you. So—and I think the rest of the committee did, and we will be transcribing this in 3 days, and you will actually be looking at the text of it. It will help us with our next hearing. So thank you so much.

This hearing is adjourned.

[NOTE.—"Procedures for Investigating Suspicious Outbreaks of Infectious Disease in a Noncooperative Environment," by Jonathan B. Tucker may be found in subcommittee files.]

[Whereupon, at 4:30 p.m., the subcommittee was adjourned.]

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