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# THE BIOLOGICAL WEAPON CONVENTION: 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 SIXTH CONGRESS

SECOND SESSION

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# THE BIOLOGICAL WEAPON CONVENTION: STATUS AND IMPLICATIONS

**WEDNESDAY, SEPTEMBER 13, 2000**

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 10 a.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays and Souder.

Staff present: Lawrence J. Halloran, staff director and counsel; David Rapallo, minority counsel; and Earley Green, minority assistant clerk.

Mr. SHAYS. The hearing will come to order.

Prohibitions against the use of toxic and biologic weapons have been found in 2000 year old Sanskrit tracts. From the Middle Ages to the 1925 Geneva Protocol, biological warfare has been justly condemned by the general opinion of the civilized world. The 1972 Biological Weapons Convention [BWC], declares germ warfare "repugnant to the conscience of mankind."

But persistent moral and political proscriptions have not prevented intermittent outbreaks of man-made biological horror.

Each of the 159 nations endorsing the BWC pledged "never in any circumstance to develop, produce, stockpile or otherwise acquire or retain" microbial or biological agents or the means to use them in war. Yet the convention contained no verification or enforcement provisions because biological weapons were not considered a significant military threat in the cold war world.

How the world has changed. Iraq's unchecked use of prohibited weapons of mass destruction against Iran in the 1980's emboldened nations and terrorist organizations who saw lethal rewards and little risk in the proliferation and use of chemical and biological arms. The demise of the Soviet Union revealed a bio-weapons program in direct violation of the BWC on an almost unimaginable scale.

According to yesterday's Washington Post, surplus Soviet biological weapons, technology and expertise may yet be made available to the highest bidder despite U.S. threat reduction efforts.

Acknowledging the need for a stronger regime to deter and detect BWC violations, representatives of signatory nations in 1995 began negotiating the terms of a compliance protocol including declaration, verification and inspection provisions similar to those con-

tained in the Chemical Weapons Convention [CWC]. The draft protocol under discussion in Geneva raises, but does not yet answer, fundamental questions about curbing the spread of biological weapons.

To what extent is the BWC verifiable? When the same microbe and the same equipment can be used to make a life saving vaccine 1 day and a deadly weapon the next, will any protocol prove more than a temporary nuisance to a determined violator? Will the uncertain benefits of a traditional arms control verification system outweigh the certain and substantive burdens on governments and private enterprises conducting legitimate medical research and pharmaceutical production activities?

How can classified material and proprietary business information be protected from an intrusive inspection regime some would use to conduct state-sanctioned spying and industrial espionage?

Recent history offers only partial answers. Efforts by the United Nations Special Commission, UNSCOM, to inspect Iraqi bio-weapons facilities demonstrated how easily a focused enforcement program can be frustrated. Experience to date under the Chemical Weapons Convention provides some comfort that procedural and substantive safeguards can work to protect the rights and the intellectual property of the inspected. But it remains uncertain whether the same safeguards will work in a very different setting in which a single microscopic organism contains the blueprint for a product or process worth hundreds of millions of dollars.

As the subcommittee begins our consideration of these important issues today, we are fortunate to be joined by the lead U.S. negotiator on the BWC protocol, Ambassador Donald Mahley, and four other wonderful witnesses, three others, excuse me, who bring a great deal of experience and expertise to this discussion. We look forward to their testimony.

Regrettably, we are not joined this morning by a representative from the Pharmaceutical Research and Manufacturers of America, PhRMA, who declined our invitation to participate. In working with the administration on these issues, PhRMA has not been shy about expressing a position in favor of a more workable, cost-effective process to control biological weapons.

As world leaders in conquering disease, American pharmaceutical companies have an unassailably positive role to play, and an undeniable responsibility to participate, fully an undeniable responsibility to participate in this discussion. We trust their timidity will be overcome at a future hearing.

At this time I would like to welcome our four witnesses. Ambassador Donald Mahley, Special Negotiator for Chemical and Biological Arms Control, Department of State. Dr. Susan Koch, Deputy Assistant Secretary, Threat Reduction Policy, Department of Defense. Mr. Roger Majak, Assistant Secretary, Bureau of Export Administration, Department of Commerce. Mr. Jack L. Brock, Jr., Managing Director, Acquisition and Sourcing Management, General Accounting Office.

We'll go in the order that I announced you. If you would, I'll invite you to stand. As you know, we swear in all our witnesses. All the time I've done this there was only one witness who didn't get

sworn in, and that was Senator Byrd, and I was just plain cowardly. [Laughter.]

[Witnesses sworn.]

Mr. SHAYS. Note for the record that all have responded in the affirmative, and I appreciate the other two standing up in case we need to call on you. So thank you.

Ambassador Mahley, what we do is we put 5 minutes on, and then we roll over for another 5 minutes. Given that we only have one panel, I'm sure 10 minutes is enough.

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

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# Statement of Rep. Christopher Shays

September 13, 2000

Prohibitions against the use of toxic and biologic weapons have been found in two thousand-year-old Sanskrit tracts. From the Middle Ages to the 1925 Geneva Protocol, biological warfare has been "justly condemned by the general opinion of the civilized world." The 1972 Biological Weapons Convention (BWC) declares germ warfare "repugnant to the conscience of mankind."

But persistent moral and political proscriptions have not prevented intermittent outbreaks of man-made biological horror.

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**STATEMENTS OF DONALD A. MAHLEY, AMBASSADOR, SPECIAL NEGOTIATOR FOR CHEMICAL AND BIOLOGICAL ARMS CONTROL, DEPARTMENT OF STATE; SUSAN KOCH, DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR THREAT REDUCTION, U.S. DEPARTMENT OF DEFENSE; R. ROGER MAJAK, ASSISTANT SECRETARY OF COMMERCE FOR EXPORT ADMINISTRATION, U.S. DEPARTMENT OF COMMERCE; AND JACK L. BROCK, JR., MANAGING DIRECTOR, ACQUISITION AND SOURCING MANAGEMENT, U.S. GENERAL ACCOUNTING OFFICE**

Ambassador MAHLEY. Thank you, Mr. Chairman.

I appreciate the opportunity to testify today on behalf of the negotiations for a protocol to the Biological Weapons Convention. I would like for a few minutes to address the overall objectives of the United States in these negotiations and current developments in Geneva.

I have also prepared a written statement, which I would submit for the record if that is acceptable.

The current negotiations have a long history. The issue of confidence and compliance with the Biological Weapons Convention has recurred in review conferences and international fora since the convention entered into force in 1975. The very fact that there already is a Biological Weapons Convention shapes the negotiations we are now undertaking. All the participants in these negotiations have already pledged to forego offensive biological warfare activities as part of the basic provisions of the convention.

The current effort is to negotiate a legally binding document that will be additional to, but not amend or interfere with, the basic convention. We have drawn heavily on both the confidence building measures instituted in 1986 and the multilateral negotiations for a Chemical Weapons Convention that were completed in 1992. Some of the lessons we have learned from that experience are very good, some are very dubious, some apply not at all.

Biology is different from chemistry or from nuclear physics. The instruments developed in other negotiations, and even the confidence building measures information from 1986 must be adapted to a rapidly changing environment. We are attempting to do that in Geneva.

The United States' objective for these negotiations has been constant. We seek to strengthen confidence and compliance with the convention by creating a regime that will gather and process information about activities relevant to the objectives of the convention. More fundamentally, we seek a regime that will provide for onsite activities, the most important of which would be investigations of an alleged violation of the convention, to deter potential proliferators and complicate their ability to develop offensive biological weapons programs.

Unfortunately, some other countries in the negotiations have different priorities. Radical non-aligned states, particularly, see this as an opportunity to institutionalize guaranteed access to dual-use technology and material. This would, of course, undermine current U.S. nonproliferation programs and policies, as well as those of other like-minded states. For the United States, that is not an acceptable element of a protocol.

There are other issues that still defy resolution. We are fighting very hard to make onsite activities ones that will provide information but not disproportionately burden the United States or put at risk either proprietary or national security information. We have not yet settled on an unambiguous universe of activities or facilities to be declared.

The United States continues to be actively engaged in the negotiations in Geneva. We do not believe, however, that an end game is in the near future. The 1996 Review Conference to the Biological Weapons Convention set as a target for completion of the ad hoc group negotiations the next Biological Weapons Convention Review Conference, which will occur in 2001. The United States intends to do all it can to accomplish that target. However, as Secretary Albright informed her allied counterparts in July, "The United States will not accept a protocol that undermines rather than strengthens national and international efforts to address the biological weapons threat."

The United States delegation in Geneva will indeed continue to exert every effort to shape the emerging document to support these objectives. We can afford to accept no less.

Thank you, Mr. Chairman.

[The prepared statement of Ambassador Mahley follows:]

**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**

**September 13, 2000**

Mr. Chairman, members of the subcommittee, I would like to express my appreciation on behalf of the Secretary of State and the Administration for this opportunity to appear before you. I understand the purpose of this hearing is to gain additional insight on the current negotiations pursuing a Compliance Protocol to the Biological and Toxin Weapons Convention. As the United States Representative to the negotiations, my testimony will focus on the state of the negotiations, developments in Geneva, and the United States view of the implications of those negotiations for national security and the potential proliferation of biological weapons.

As a brief background, let me review the development of these negotiations. You are familiar with the fact that the Biological and Toxin Weapons Convention, commonly referred to as the BWC, entered into force in 1975, and now has expanded to include 143 states as parties to the Convention. The BWC is one of the few arms control agreements having no verification or compliance provisions. In order to review the functioning of the Convention, the States Parties convene a Review Conference every five years. In the 1986 Review Conference, the States Parties agreed that parties should submit, on an annual basis, a series of declarations about certain biologically-related activities in their respective countries. These "confidence building measures", which were not legally binding, were designed to provide additional confidence to all States Parties that countries were not engaging in clandestine offensive biological weapons development or production. The content of these measures was expanded (or "enhanced") at the 1991 Review Conference.

By the time of the 1991 Review Conference, there was dissatisfaction with the efficacy of the confidence building measures. Many countries were not submitting annual reports. In fact, as of today, only some 75 States Parties have ever submitted an annual confidence building measures report, even though all States Parties agreed to provide "negative reports" when there were no activities. As a result of such incomplete responses, at the 1991 Review Conference the States Parties decided to undertake a more rigorous examination of potential ways to strengthen the BWC.

The final document of the 1991 Review Conference established the "Ad Hoc Group of Governmental Experts" (later known by the nickname "Verex") to explore potential measures to strengthen the BWC. This group met frequently for over two years, and produced a report containing 21 measures they recommended for further study as potential mechanisms to strengthen the BWC.

In 1994, the States Parties convened a Special Conference to review and accept the report of the Ad Hoc Group of Experts. The final document of the Special Conference established a further group, the Ad Hoc Group of States Parties to the Biological and Toxin Weapons Convention, chartered to develop a legally binding addition to the BWC (a Protocol) to strengthen confidence in compliance with the Convention.

That Ad Hoc Group has been meeting several times a year in Geneva since 1995 in an effort to negotiate such a Protocol. I would note that even though the negotiations have been spread over five years, if we took the Conference on Disarmament schedule as a model, the total time of active negotiation would amount to only two years in the Conference on Disarmament. These are the negotiations that we are providing a status report on today. I apologize for this detailed history, but the lineage of the Ad Hoc Group is relevant to the nature of the negotiations and the issues now outstanding in the draft Protocol.

At the 1996 Review Conference of the BWC, the States Parties agreed as part of the consensus final document to urge the Ad Hoc Group to expedite its work. They set as a target date for completion of a Protocol and its recommendation for adoption by all States Parties the timing of "as soon as possible before the next Review

Conference." The Review Conference in question is scheduled for 2001, likely in November. The impending arrival of the target date has had the effect, as Mark Twain once observed in a different context, of "focusing the minds" of the participants in the negotiations on prospects for completing a Protocol in the remaining time. As Secretary Albright has informed key allied counterparts, and as Under Secretary Holum has told the Ad Hoc Group, we still hope a satisfactory Protocol can be achieved by the 2001 target date. Substantial progress has been made in Geneva over the past year toward achieving this goal. But the United States will not accept a Protocol that undermines rather than strengthens national and international efforts to address the BW threat.

There is much serious work still to be done. I will not try to catalog all of the outstanding issues. However, some of the most crucial include:

- How will on-site activities allow for the protection of both national security information not connected to biological weapons activity and commercial proprietary information of great intellectual and financial value to our industry?

- How will the Protocol protect the United States, with the largest biodefense program in the world, from having to reveal either the promising defensive capabilities we are exploring or the areas of vulnerability where we have not yet been able to find appropriate biodefense against a potential enemy?

- How will the United States be able to continue to work with like-minded states to stem the potential proliferation of biological weapons capability to states of concern by reducing, or at least complicating, their access to the equipment, technology, and materiel that would most easily be misappropriated for illicit purposes?

These and other questions must be answered constructively for the United States to be able to accept the outcome of the negotiations. At the same time, answers that are constructive from our perspective may be contrary to the wishes of other participants in the negotiations. Thus, having made a lot of progress in the negotiations does not

mean we have reached a point where an "end game" is either present or on the predictable horizon.

One of the things that makes progress in the negotiations unpredictable is the unique nature of this effort when compared to the other experiences usually cited as models for our work. A classic example of an overstated parallel is with the Chemical Weapons Convention.

One of the levers available to forge a successful conclusion to the Chemical Weapons Convention negotiations was the fact that the Convention provided the legal basis for banning chemical weapons. This was a valuable component of the overall Convention. In the biological weapons case, the ban on such weapons is already in place, and has been since 1975. This means that in the negotiating dynamic between the states seeking greater security and the states seeking greater access to technology and benefits, the security benefit is weakened.

Conversely, security costs associated with any protocol would also differ. The same pre-existing ban on BW reflected in the Convention means there would be no forfeited military option by agreeing to a BWC Protocol.

The *a priori* existence of the BWC complicates negotiating trade restrictions against non-parties to the Protocol. In the Chemical Weapons Convention, trade with non-parties in Schedule 2 chemicals was deliberately prohibited three years after entry into force. This was done in part to provide an economic incentive for states to join the Convention.

There are states proposing a like ban on trade in some biological technology, equipment, and materiel with those states that choose not to become parties to the Protocol. However, only States Parties to the BWC are eligible to become parties to the Protocol. Thus, all the future parties to the Protocol will previously have undertaken the obligations of the BWC, including those in Article X of that Convention. Article X says that you shall implement the Convention in a fashion to "...avoid hampering the economic or technological development of States Parties to the Convention...."

An outright ban on trade in some biological commodities against other states that are party to the Convention but

not to the Protocol would thus contradict the Article X obligation in the BWC. We can debate the utility of such an incentive tool. However, it is simply not available in this instance.

The Chemical Weapons Convention is also frequently cited as a parallel because of its provisions to protect proprietary information during on site-activities at commercial installations. However, the nature of proprietary information is very different between the chemical and biological industries. Some entities, including both states and non-government organizations, argue that the success of the Chemical Weapons Convention and the relatively straightforward procedures used to protect industry interests there means that biological firms are equally safe from damaging disclosure under any BWC Protocol regime.

In one sense, there is an accurate parallel between the Chemical Weapons Convention and the draft BWC Protocol. That is the *principle* of "managed access." This principle is the concept that national security or proprietary information rightfully can be protected during an on-site activity, by devising alternative methods to those requested by members of the international organization to answer any questions they ask. However, application of the principle is very different between chemistry and biology. While proprietary or national security concerns have proven to be relatively localized and manageable in Chemical Weapons Convention inspections, there is legitimate concern that managed access could be much more complicated to apply in the context of activity at a biological facility, and thus while being useful, would not necessarily provide the level of security we require.

To supplement managed access, the United States is seeking other provisions to the Protocol to add protection. These include tightly crafted declaration language, provision for a majority vote in the international organization before a clarification visit or investigation could be authorized, timelines to allow thorough preparation of a facility in advance of a visit or investigation, and far less intrusive activities in any non-challenge visit.

I would only point out a few fairly simple differences.

- The most sensitive proprietary elements of chemical processes frequently are temperature, pressure, duration, and proprietary catalysts to improve the reactions. The relevant interaction of corrosive chemicals takes place inside opaque reactor vessels. Thus, by concealing the computer monitoring screens and controlling sampling, the proprietary values can be protected. In biology, the very configuration of the operation or the kind of media being used to stimulate activity is frequently proprietary, and much more difficult to mask.

- In chemical reactions, it is reasonably straightforward to do mass balancing equations to demonstrate what reactions are being carried out. In biology, given the living nature of some of the activity, such input-output balancing is not sufficient to demonstrate the nature of the intermediate activity.

- A sample of a chemical product will only confirm that which has already been stated - what the product is. In biology, even a small process or proprietary organism sample could well reveal not only what the product is, but the proprietary process from which it was produced.

These difficulties do not mean that managed access can not be used successfully during BWC Protocol on-site activities, or that we have not learned several useful lessons from previous negotiations to guide work on the BWC Protocol. However, the nature of biotechnology will complicate employment of managed access provisions.

In the Chemical Weapons Convention negotiations and PrepCom, a great deal of effort was devoted to making declarations as unambiguous as possible. Despite those efforts, it has required a great deal of outreach work by the United States Government and the American Chemical Council to make our own declarations as accurate as possible. Even then we have not achieved total accuracy in the initial declarations. Other countries have done an even less accurate job.

This result puts severe pressure on the task of drafting declarations for the BWC Protocol. The correspondence of information provided by declarations to unique capability for biological weapons work is more dubious. Thus, we have tried to focus on the <u>most relevant</u> activity for declaration. However, a much wider variety of activities

could become part of a BW capability. A much smaller magnitude of activity is required to reach a militarily significant capability.

At the same time, since there are legitimate activities involving the same kind of actions and even the same materials, the issue of compliance hinges largely on intent. This means that accusations could require addressing the issue of "things not being done." You recognize the logical difficulty which proving such a negative premise entails.

All of this means that the U.S. and the Ad Hoc Group face a real challenge to develop a set of declaration requirements that will be

- relevant to possible proliferation activity;
- unambiguous enough to be accurately declared by both U.S. government facilities and commercial facilities;
- widely enough located in the world to provide access to countries of concern;
- not overly burdensome on U.S. activities or unbalanced, either from a commercial or security perspective;
- free from the political complication of leaving unanswered questions that could impair the ethical reputation of U.S. facilities.

I have outlined a number of remaining issues and obstacles to reaching a useful agreement in Geneva. I do not wish to convey the impression that there is no potential benefit from a satisfactory Protocol, nor that it is a hopeless technical problem. It is extraordinarily difficult, but that makes it a worthy challenge.

First of all, this is not an issue of verification. As you know, the United States has substantive requirements for attributing effective verifiability to a treaty. It involves being able to make a judgment of high confidence in detecting a violation before it can become a militarily significant threat. I have already noted that a small program can become a threat. Likewise, the inherent "cover" for an illicit program in legitimate activity makes

differentiation much more imprecise. The United States has never, therefore, judged that the Protocol would produce what is to us an effectively verifiable BWC.

There is, however, real value in increasing the transparency associated with biological activity. What we have sought in the negotiations is greater transparency into the dual-capable activities and facilities that could be misdirected for BW purposes. This could, in our view, complicate the efforts of countries to cheat on their BWC obligations.

Let me be clear - the United States already faces a BW proliferation problem. Our objective for a Protocol is to enable us to gain more information about and insight into activities of potential concern.

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 "whistle-blower" prospect of an employee or the ineptitude of a cover-up of an illicit activity. While there is no way to judge the likelihood of such an outcome, the deterrence component is useful since it complicates the life of a potential proliferator.

The obverse of the previous proposition is the issue of impact on United States installations and firms from the same kind of on-site activity. The differences between chemical and biological technologies, as well as the different challenges in defining total prohibition of chemical weapons in the Chemical Weapons Convention vice the prohibition of only offensive BW activity in the BWC remain relevant. However, there are some principles learned in the Chemical Weapons Convention that inform the procedures we are negotiating for the BWC Protocol.

The principle of managed access, we believe, can effectively prevent loss of national security or proprietary information, while still allowing U.S. installations to demonstrate the benign nature of their activities. With respect to private sector installations, I would like to assure the committee that the executive branch is fully cognizant of our responsibility to be a

supportive interlocutor with the international organization conducting on-site activity.

The Chemical Weapons Convention inspections already conducted on both Department of Defense facilities and at commercial firms have thus far demonstrated our ability to fulfill the obligations of the Chemical Weapons Convention without sacrificing sensitive national security or commercial proprietary information. We are using the lessons and experience learned to explore ways to achieve an equal level of protection in biological activities, and we are confident we can do so by the time any BWC Protocol is in place.

The advantage United States installations possess is that we have a good story to tell. Our commercial firms are actively engaged in researching, developing, and producing products that benefit mankind. Our defense installations are pursuing ways to detect biological weapons early enough to minimize their impact and to protect our armed forces and civilian population in the event of a biological weapons attack. We believe, if the declaration requirements and on-site access provisions are properly crafted, it is possible to portray those efforts completely enough to satisfy any on-site interrogator while still protecting the sensitive elements of the activity. Thus, the impact on U.S. facilities should be manageable, while the value of on-site activity in other countries to transparency and our BW nonproliferation efforts is real.

This statement has attempted to address the specific topics raised by the committee, as well as to provide a general picture of the current negotiations. I would be happy to answer any questions.

Mr. SHAYS. Thank you, Ambassador.

Dr. Koch.

Dr. KOCH. Thank you, Mr. Chairman.

I, too, appreciate the opportunity to appear before you today to provide Department of Defense perspectives on the negotiations for an enforcement protocol for the Biological Weapons Convention. I have provided a written statement which I would ask to be submitted for the record.

The Department of Defense fully supports the effort to achieve a BWC protocol that would assist in our larger effort to prevent and respond to the proliferation of weapons of mass destruction. As Ambassador Mahley has described, biological weapons by their very nature pose a much more difficult arms control challenge than other technologies, leading to limited utility for traditional arms control verification tools.

But a BWC protocol can definitely strengthen confidence in BWC compliance, by enhancing international transparency, and thus making an important and useful contribution to our nonproliferation efforts.

In that regard, a protocol must complement the nonproliferation and counter-proliferation tools that we already have, and which we are striving to buttress. Specifically, a protocol must not undermine our own bio-defense programs or those of our friends or allies, nor must it in any way weaken the existing system of nationally based export controls. And finally, we must protect sensitive national security activities that are not relevant to biological weapons technology. The Defense Department is confident that current U.S. negotiating positions in the protocol negotiations adequately protect these vital national security equities.

If I could briefly discuss the three critical areas of export controls, bio-defense and related declarations and onsite activities. First on export controls. Our position on this aspect of the BWC protocol is unambiguous. Given the national security importance of effective biological weapons-related export controls, we would not support a protocol that proscribes, curtail or otherwise undercuts national export controls or multilateral political arrangements, such as the Australia Group.

Second, on biodefense. Despite our best efforts, nonproliferation and arms control measures will not for the foreseeable future eradicate the threat of biological weapons proliferation. Therefore, the Defense Department is focusing an unprecedented amount of resources on improving U.S. biodefense capabilities.

Planned DOD expenditures for defense against chemical and biological weapons will total well over $5 billion for fiscal years 2002 through 2007 for research, developing, testing, evaluation and procurement. Our biodefense program focuses on multiple areas, including collective and individual protection, detection, treatment and decontamination, and involves numerous government, contractor and academic facilities of various sizes.

We have designed our approach to the treatment of biodefense and associated declarations in a BWC protocol to meet three basic objectives, in keeping with the size, importance and purpose of our biodefense programs. First, to allow consistent accurate implementation; second, to maximize the likelihood that activities and coun-

tries of concern would be captured; and third, not to reveal gaps and vulnerabilities in U.S. biodefense efforts and those of our allies.

Closely related to declarations is the issue of onsite activities, such as visits and investigations. Such onsite activities are key measures for enhancing transparency. At the same time, we must protect sensitive national security activities that may be located in visited facilities or within investigation areas, but which are not relevant to the BWC. Here, too, we are confident the current U.S. negotiating positions will allow us to do this.

DOD has long and extensive experience in implementing onsite provisions of modern arms control treaties, including implementation at DOD facilities and protection of national security assets. Although that experience is not completely directly transferable to the BWC protocol, some lessons can be learned, particularly from our experience with the Chemical Weapons Convention [CWC].

Since the CWC entered into force in 1997, the Organization for the Prohibition of Chemical Weapons' inspectors have participated in the United States in 56 inspections at 12 former chemical weapons production facilities, 47 inspections at 13 chemical weapons storage facilities, 7 inspections at 2 schedule one production facilities, and 1 transparency visit at a destructionsite. Each of those typically averages 3 to 6 days.

Additionally, there have been 160 rotations of continuous monitors at chemical weapons destruction facilities, with monitors typically onsite for 3 to 6 weeks. The sum total of the monitor rotations and the visits and inspections have been 270 separate onsite activities at DOD facilities from Chemical Weapons Convention entry into force through the end of August 2000.

There have been no CWC challenge inspections to date, but the military services have held exercises to test their preparedness for this possibility. And DOD is organizing a mock challenge inspection for next year, with actual inspectors from the Organization for the Prohibition of Chemical Weapons.

To the best of our knowledge, none of these extensive CWC activities has resulted in any disclosure of sensitive information, whether inadvertent or otherwise. At the same time, the costs involved, while hardly insignificant, have proved less than might have been expected. Between entry into force in April 1997 and June 1999, which are the most recent figures available, DOD spent approximately $26 million directly related to supporting Chemical Weapons Conventions inspections. All told, total DOD costs for preparation and execution of the CWC from fiscal year 1992 through fiscal year 2001 amount to slightly over $518 million.

Under the current U.S. negotiating position, a BWC protocol would afford to us the same or greater ability to protect sensitive national security information at lower cost.

Compared to CWC, the onsite activities that the United States supports for a BWC protocol would be less intrusive, much fewer in number, smaller in scale, shorter, and spread among a much larger universe of facilities. While CWC offers a very interesting basis for comparison with the planned BWC protocol and gives us many lessons that we can apply to good use, it's also important to work to understand the differences between the two, both to assist

in developing our negotiating positions and to prepare for eventual implementation.

Early in the negotiations, in October 1995, DOD conducted a trial visit of a vaccine facility in the United States. This trial underscored for us the unique challenges posed in dealing with dual-use cutting edge biological technologies. Currently, DOD is preparing to participate in national trial visits and inspections as mandated by H.R. 3427.

We're well along in our planning, including identifying funding, appropriate facilities both onsite and analytic personnel. We hope to conduct an initial transparency visit exercise later this year or early next year at a DOD facility.

We've also worked to ensure that facilities that are likely to be affected are fully apprised of negotiating developments. For example, over the past 2 years, my staff has provided classified quarterly briefings to representatives from concerned Defense Department and defense industry representatives, soliciting their reactions to various proposals under consideration at the protocol negotiations. This feedback has helped to shape U.S. Government positions on issues such as visits and declaration triggers and formats.

In sum, the BWC protocol negotiations are exceptionally complex. The problem they deal with is unprecedented in its difficulty. But our prior experience and continual consultation with concerned U.S. Government and defense industry elements reinforces our conviction that under the provisions envisioned in the current U.S. negotiating position, we will effectively protect our national security interests.

Thank you, Mr. Chairman.

[The prepared statement of Ms. Koch follows:]

Testimony of Dr. Susan Koch
Deputy Assistant Secretary of Defense
for Threat Reduction Policy

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

**The Biological Weapons Convention: Status and Implications**

13 September 2000

Mr. Chairman, members of the Subcommittee, I appreciate the opportunity to appear before you today to provide Department of Defense (DOD) perspectives on the negotiations to complete an enforcement and compliance protocol for the Biological and Toxin Weapons Convention (BWC). DOD has been an active participant in these negotiations from the beginning. Over the past five years we have worked to help develop a legally-binding instrument to strengthen confidence in BWC compliance by providing greater transparency into relevant programs and activities.

The Department of Defense fully supports the goal of achieving a Protocol that augments our national security. A credible Protocol will provide an additional tool to assist in our larger effort to respond to the proliferation of weapons of mass destruction. However, it is important to acknowledge that biological weapons by their very nature pose a more difficult arms control challenge than other technologies. The items and activities covered by the BWC are nearly all dual-use; they are based on equipment and technology that have legitimate commercial and/or defensive purposes. Moreover, the time needed to convert legitimate production facilities for prohibited uses is often very short, in some cases a matter of hours. Furthermore, unlike chemical weapons, comparatively small amounts of biological weapons can be militarily significant, and can be produced relatively quickly. Thus, unlike chemical weapons, large-scale stockpiles are not required. Taken together, these factors all serve to limit the utility of traditional arms control verification tools.

As Ambassador Mahley has just explained, we do not believe that the Protocol being negotiated will be able to provide the kind of effective verification that exists in other arms control treaties. That is, it will not provide a high degree of confidence that we could detect militarily significant cheating. We therefore recognize that this Protocol will not "solve" the problem of biological weapons proliferation, even among the BWC States Parties who opt to join. But it can contribute to the more limited goal of strengthening confidence in BWC compliance by enhancing international transparency in the biological sphere. We see this as an important and useful contribution to our nonproliferation efforts.

In pursuing the Administration's goals, the Defense Department has worked to ensure that U.S. negotiating positions support a Protocol that would complement the nonproliferation and counterproliferation tools that we already have – and which indeed we are striving to buttress. These existing tools play indispensable roles in impeding proliferation and managing its consequences. Specifically, a BWC Protocol must not undermine our own biodefense programs

or those of our friends and allies. Likewise, we must ensure that it does not in any way weaken the existing system of nationally-based export controls, which continues to serve us well. Finally, we must protect sensitive national security activities that are not at all relevant to biological weapons technology.

Let me stress that the Defense Department is confident that current U.S. negotiating positions adequately protect these vital national security equities. The elements of the negotiations that most directly affect Defense equities are measures being considered on biodefense and related declarations, on-site activities, and export controls.

Let me turn first to this last issue, since in some ways it is the simplest and most straightforward. The national security importance of preserving effective biological weapons-related export controls is obvious. Such nonproliferation tools remain a proven means to impede proliferation. Our position on the potential relationship between a BWC Protocol and export controls is therefore very unambiguous. We would not support a Protocol that proscribes, curtails, or otherwise undercuts national export controls or multilateral political arrangements such as the Australia Group. Such multilateral regimes are vital to facilitate voluntary cooperation among like-minded states. Nor would we support any negotiating outcome that would infringe on States Parties' sovereign right to deny exports on a national basis, as they deem fit.

Recognizing that despite our best efforts, nonproliferation and arms control measures will never completely eradicate the threat of biological weapons proliferation, the Defense Department also places an extremely high priority on the ability to manage the consequences of any biological weapons proliferation or use. We continue to bolster our military preparedness to operate and prevail in a biological weapons environment. As part of our wider Counterproliferation Initiative, the Defense Department is focusing unprecedented resources on improving U.S. biodefense capabilities. Other agencies are involved in closely related efforts. Planned expenditures for defense against chemical and biological weapons total well over $5 Billion in DOD alone for Fiscal Years 2002-2007 for research, development, testing, and evaluation (RDT&E) and procurement. Our biodefense program focuses on multiple areas including collective and individual protection, detection, treatment, and decontamination, and involves numerous government, contractor, and academic facilities of various sizes.

We are also working to increase biodefense cooperation with friends and Allies. Within NATO, the high-level Defense Group on Proliferation (DGP) continues to work to expand biodefense cooperation. For example, just this past July, the DGP sponsored a major biodefense seminar in Budapest, drawing together an impressive array of technical experts and policy officials. Additionally, the United States now has over sixty individual cooperative agreements in chemical and biological defense with more than twenty friends and allies around the world. These bilateral agreements span a broad spectrum of biodefense activities.

Because the U.S. biodefense program is so much larger than any other, it is inevitable that the United States will bear the greatest burden under any relevant BWC Protocol declaration requirement, including those that we ourselves are proposing. With that in mind, we have designed our approach to the treatment of biodefense and associated declarations in a BWC Protocol to meet three basic objectives. These are to: (1) allow consistent, accurate

implementation; (2) maximize the likelihood that activities in countries of concern would be captured; and, (3) not reveal gaps and vulnerabilities in U.S. biodefense efforts and those of our Allies. Our proposal seeks to achieve these goals by focusing on those current research and development (R&D) activities that are the most relevant for potential non-compliance (i.e. pathogenicity, virulence, aerobiology, and toxinology), at sites conducting more than a specified "level of effort". Thus, declaration requirements would be based on a combination of the type of work and the amount of work on relevant activities at a given facility. At the same time, we are also seeking to include a minimum declaration requirement, in order to ensure that countries of concern that might have relatively small biodefense programs will nonetheless have to declare them.

Closely related to declarations is the issue of on-site activities, such as visits and investigations. We expect that these will most often involve visits to declared facilities. Such on-site measures are a key element for enhancing transparency. At the same time, it is imperative for us to be able to protect sensitive national security activities that may be located in visited facilities or within investigation areas, but which are not relevant to the BWC. Here too we are confident that current U.S. negotiating positions will allow us to do this.

DOD has long and extensive experience in implementing on-site provisions of modern arms control treaties, including the Intermediate Nuclear Forces (INF) Treaty, the Conventional Forces Europe (CFE) Treaty, the Strategic Arms Reduction Treaty (START), and the Chemical Weapons Convention (CWC). Most of this experience relates to implementation at DOD facilities and protection of national security assets. At the same time, we must recognize that on-site activities for BWC will be very different from other treaties, including CWC. For example, BWC visits will monitor activities that are not prohibited, or even restricted, by the Convention. Nonetheless, that experience, particularly in CWC, offers some useful lessons for BWC regarding our ability to protect sensitive information and the possible costs involved.

Since CWC entered into force, approximately 215 inspectors from the Organization for the Prohibition of Chemical Weapons (OPCW) have participated in on-site activities at DOD facilities. These include more than 270 visits and inspections of typically 3-6 days at 47 chemical weapons storage and 56 former production facilities, as well as continuous monitoring at chemical weapons destruction facilities. The Office of the Secretary of Defense has centrally overseen and managed the preparation for and hosting of CWC inspections, through a DOD Chemical Weapons Agreements Implementation Working Group. The Military Services and various DOD components have individually established implementation support offices which actively participate in this process. In addition to more general treaty familiarization courses, the Defense Threat Reduction Agency's (DTRA) Defense Treaty Inspection Readiness Program (DTIRP) provides training on facility preparation and security countermeasures to government and defense-industry facilities. Although there have been no CWC challenge inspections to date, the Military Services have held exercises to test their preparedness for this possibility, and DOD has developed guidance, exercised procedures, and is organizing a mock challenge inspection for next year with actual OPCW inspectors.

To the best of our knowledge, none of these CWC activities has resulted in the disclosure of sensitive information, inadvertent or otherwise. At the same time, the costs involved have

**CORRIGENDEM**

**Testimony of Dr. Susan Koch**
**Deputy Assistant Secretary of Defense for Threat Reduction Policy**

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

**The Biological Weapons Convention: Status and Implications**

**13 September 2000**

Data was inadvertently omitted from Page 3, second paragraph from bottom. This paragraph should read as follows:

Since CWC entered into force through 23 August 2000, approximately 215 inspectors from the Organization for the Prohibition of Chemical Weapons (OPCW) have participated in on-site activities at DOD facilities. There have been a total of 56 inspections at 12 former chemical weapons production facilities, 47 inspections at 13 chemical weapons storage facilities, 7 inspections at 2 Schedule 1 production facilities, and one transparency visit at a destruction site. These typically have lasted 3-6 days. Additionally, there have been 160 rotations of continuous monitoring inspectors at chemical weapons destruction facilities, with inspectors typically on site for 3-6 weeks. All told, there have been more than 270 discreet on-site activities. The Office of the Secretary of Defense has centrally overseen and managed the preparation for and hosting of CWC inspections, through a DOD Chemical Weapons Agreements Implementation Working Group. The Military Services and various DOD components have individually established implementation support offices, which actively participate in this process. In addition to more general treaty familiarization courses, the Defense Threat Reduction Agency's (DTRA) Defense Treaty Inspection Readiness Program (DTIRP) provides training on facility preparation and security countermeasures to government and defense-industry facilities. Although there have been no CWC challenge inspections to date, the Military Services have held exercises to test their preparedness for this possibility, and DOD has developed guidance, exercised procedures, and is organizing a mock challenge inspection for next year with actual OPCW inspectors.

proved less than might have been expected when the negotiations began. Between CWC entry into force in April 1997 and June 1999 (the most recent figures available), DOD spent approximately $26 Million directly related to supporting CWC inspections. This included funding for dispatching advance teams to DOD facilities undergoing inspection, and providing transportation and accommodations for inspectors and DOD escorts. All told, total DOD costs for preparation and execution of CWC declaration and inspection requirements from Fiscal Year 1992 through Fiscal Year 2001 amount to approximately $518 Million (excluding relatively low-cost cross treaty site preparation costs by special programs offices and DTIRP). This total includes funding for determining declarable items and facilities, assembling declarations, developing implementation plans for routine and challenge inspections, conducting practice routine and challenge inspections, and conducting research and development for improving verification and compliance activities and reducing impacts of those activities on DOD facilities.

Under the current U.S. negotiating position, a BWC Protocol would afford to us the same or greater ability compared to the CWC to protect sensitive national security information, with lower associated costs.

Compared to CWC, the on-site activities that the United States is arguing for in a BWC Protocol would be less intrusive, far fewer in number, smaller in scale, shorter, and diffused among a dramatically larger universe of facilities. We are proposing visits to a limited number of BWC-relevant facilities to increase transparency, promote fulfillment of declaration obligations, and familiarize a BWC Technical Secretariat with a country's biotechnology and biodefense infrastructure – not inspections at declared facilities to validate declarations that last up to a week. All visits and investigations would allow the United States to manage access through provisions equivalent to or even more protective than in CWC. Additionally, as in CWC, the U.S. is insisting that a Protocol include sufficient timelines between notification and commencement of visits or investigations, in order to allow time for site preparation. The U.S. is also seeking a distribution formula that would ensure that no State Party receives more than 20 non-challenge visits per five years, with no more than two of these at any one facility. Finally, in contrast to CWC, a Protocol would involve no continuous monitoring requirements.

I must reiterate that, while CWC offers an interesting basis for comparison with the planned BWC Protocol, there are likely to be as many differences as similarities. We therefore have endeavored to understand the implications of these differences, both to assist in developing our negotiating positions, and to prepare for eventual implementation. Early in the negotiations, in October 1995, DOD conducted a trial visit at a vaccine production facility. This trial underscored for us the unique challenges posed in dealing with dual-use, cutting edge technologies. Lessons learned included the importance of setting achievable objectives and the need for clearly articulated procedures. Currently, DOD is preparing to participate in National Trial Visits and Inspections as mandated by HR 3427. We are well along in our planning, including identifying funding, appropriate facilities, and both on-site and analytic personnel. We are working with other agencies to integrate DOD activities into the Administration's wider National Trial Visit/Inspection effort, with the goal of conducting an initial "transparency visit" exercise later this year or early next year at a DOD facility.

In addition to differences between CWC and BWC inspection modalities, BWC measures will for the most part focus on a different universe of facilities. We therefore have worked to ensure that facilities that are likely to be affected are fully apprised of negotiating developments. For example, over the past two years my staff has provided classified quarterly briefings to relevant DOD elements and defense industry, soliciting reactions to various proposals under consideration at the Protocol negotiations in Geneva. This feedback has helped to shape USG positions on issues such as visits and declaration triggers and formats.

There is no question that there will be a steep learning curve in implementing the on-site provisions of a BWC Protocol, as is always the case whenever a new arms control treaty enters into force. That said, our prior experience and continual consultation with concerned DOD, other USG, and defense industry elements reinforces our conviction that, under the provisions envisioned in the current U.S. negotiating position, we can effectively protect national security assets.

Mr. Chairman, this is a complex negotiation, and I have only addressed some of the many negotiating issues, that are of particular concern to the Department of Defense. I would be pleased to answer any questions that you or other members of the Subcommittee may wish to pose. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you, Dr. Koch.

What I'd like to do, I'd like to get some business out of the way while we have a member present, so that your statement can be in the record. 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.

And without objection, so ordered.

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

Mr. Majak, let me just interrupt you as well to welcome Mr. Souder. Do you have any statement you'd like to make?

Mr. SOUDER. No, thank you.

Mr. SHAYS. I think what we will do is we will vote, come back right away, and that way we can continue with some flow. I'm sorry, it will probably take us 10 minutes to go vote and come back.

[Recess.]

Mr. SHAYS. OK, Mr. Majak, why don't you begin your testimony.

Mr. MAJAK. Mr. Chairman, I too thank the subcommittee for this opportunity to testify on the negotiations relating to a protocol on the Biological Weapons Convention, and particularly the potential impact of such a protocol on U.S. industry.

Better international monitoring of activities at biological facilities throughout the world is of as much potential benefit to private industry as it is to governments and the public. The U.S. pharmaceutical and biological industry is devoted to sustaining and enhancing human and animal life, not threatening it. An international protocol that would help confirm that U.S. commercial facilities have no involvement whatsoever with biological weapons would be an asset for U.S. industry, especially if there should be an outbreak of disease or some other indication of biological weapons development or use.

Consequently, we at the Commerce Department and we in the administration have had a considerable degree of cooperation from industry regarding both their recommendations and their concerns about a biological weapons protocol. As has been noted, the Chemical Weapons Convention is the first such convention to include inspections in the private industrial sector.

Although we have learned a good deal about onsite monitoring and inspection under the CWC, there are significant differences between chemical and biological agents and their industrial uses, making the CWC a less than perfect model for a BWC industrial monitoring protocol. Let me give a few comparisons that are based upon the 10 chemical industry inspections we at the Commerce Department have hosted and managed so far in the United States.

First, confidential business information, the intellectual property and other information that make U.S. companies competitive is more pervasive at biological sites than in the more mature chemical industry. Much information we've found on chemical production has been published and is already in the public domain. In chemical plants, CBI is often concentrated in a particular catalyst or production technique which can be withheld from inspectors relatively easily.

By contrast, far less biological production information has been published, and a biological company's confidential information can be contained, for example, in the very genetic material of a living organism. Because microorganisms grow and reproduce and change, simply observing what goes into the plant and what goes out, which is known in the chemical weapons inspection business as a mass balance inspection, simply doesn't work for biological facilities.

So it will be tempting to use more intrusive inspection techniques, such as sampling. But with a biological sample, inspectors could have access to intellectual property that a company and its stockholders have invested huge resources to develop, and could even reproduce it in large quantities. So sampling as an inspection technique in biological facilities is out of the question.

To further complicate matters, biological agents are naturally occurring. And the equipment capable of developing and cultivating them is the same as is widely used in such common industry facilities as breweries, bakeries, waste management plants and the like. Modern biological facilities are capable of complete sterilization in a matter of hours, making discovery of weapons activities extremely difficult.

In short, there are no reliable, tell-tale signs of biological weapons activities. This makes it difficult to define and limit the range of facilities that would be covered by a protocol. In addition, the chances of a false positive finding is much higher in the biological area. And that's a great concern, of course, to companies whose good reputations, which is their most valuable asset, could be falsely tarnished.

These and other obstacles to effective biological weapons inspections, however, do not mean that a worthwhile BWC protocol is impossible. There are potential solutions for these problems, which are mentioned in my full statement. Our experience with the CWC confirms that it is possible to meet the requirements of a relatively rigorous international inspection regime, namely the CWC, without revealing confidential business information or national security information.

In the inspections that we have hosted so far, while inspection issues have arisen, all inspections have been completed and there have been no findings of non-compliance. And we have not had to force any company to disclose information it did not wish to disclose.

But the solution to a biological protocol does not reside in simply duplicating the CWC. And that is not our goal. Each regime must be carefully tailored to the realities of the proliferation threat and the industry to which it is addressed. The U.S. negotiating position reflects the need to find solutions to the special problems posed by biological agents and their production, and Ambassador Mahley has described some of those. That involves, as he noted, sometimes resisting the demands of other nations who would seek to impose CWC-like solutions.

For its part, if authorized and funded by the Congress to do so, the Commerce Department is prepared to undertake the same efforts to assist the biological industry that we have provided and are providing to the chemical industry. And those are described in fur-

ther detail in my written statement. The Commerce Department's mission is to minimize the cost burden and risk of inspections for the industrial sites being inspected, to help industrial sites that are subject to visitors or inspection to protect their confidential business information while also fully satisfying U.S. treaty obligations to provide access to those commercial activities.

Mr. Chairman, the stakes in these negotiations are high for U.S. industry, which is the world's pharmaceutical and biotechnology leader. We can best assure necessary industry support for a BWC protocol by building upon the cooperation we have received and are receiving from industry in the CWC area and by taking commercial realities fully into account in the BWC protocol negotiations as we are presently doing.

Thank you.

[The prepared statement of Mr. Majak follows:]

**Testimony of The Honorable R. Roger Majak**

**Assistant Secretary of Commerce for Export Administration**

**Before The**
**House Subcommittee on National Security, Veterans Affairs, and International Relations**
**The Biological Weapons Convention: Status and Implications**

**September 13, 2000**

Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to discuss the efforts underway to negotiate a Protocol to the Biological Weapons Convention (BWC), and particularly the potential impact such a Protocol could have on U.S. industry.

The Department of Commerce fully supports efforts to reduce the threat posed by biological weapons. A greater degree of monitoring and transparency with respect to activities at biological facilities throughout the world is of potential benefit not only to governments and the general public, but to private industry as well.

The U.S. is the world leader in pharmaceuticals and bio-technology. Next to its intellectual property, industry's greatest asset is its hard-earned reputation for integrity and product quality. It is an industry devoted to sustaining and enhancing life, not threatening it. So an international Protocol that would help confirm that U.S. commercial facilities have no involvement whatsoever with biological weapons would be a valuable asset for U.S. industry, especially in the event of an outbreak of disease or other evidence alleging biological weapons development or use. For that reason, we have had considerable cooperation from industry in the form of advice and technical assistance regarding both their recommendations and their concerns about a biological weapons Protocol.

As Ambassador Mahley has explained, it is not our goal to duplicate the chemical weapons inspection regime for biological sites. Significant differences between chemical and biological agents and their industrial uses make the Chemical Weapons Convention (CWC) regime less than a perfect model for a BWC Protocol. That is particularly apparent in the industrial setting. One major challenge of these negotiations is that other governments -- including many with little or no industry at stake -- continue to press for CWC-like provisions and requirements.

The U.S. position in the BWC negotiations, which Ambassador Mahley has described, fully reflects the differences between CWC and BWC. To better appreciate those differences and the U.S. position, let me briefly describe our experience to date with U.S. industrial inspections under the CWC and the lessons we have learned that are applicable to a BWC Protocol.

For industry, the CWC regime has two basic components: declarations and inspections. Under the CWC Implementation Act (P.L. 105-277), every U.S. facility that produces, processes or consumes internationally listed weapons-usable or precursor chemicals above specific volume thresholds must submit a declaration to the Department of Commerce. The amount of information required in the declaration varies with the type of chemical involved. Responses to certain questions are automatically classified as confidential business information (CBI) and must be protected by both the U.S. Government and the Organization for the Prohibition of Chemical Weapons (OPCW). Facilities may also indicate whether any CBI is contained elsewhere in the declaration. Once the Department of Commerce has completed a quality control review, these declarations are compiled and relayed to the OPCW. The OPCW determines which facilities have surpassed the thresholds for inspection, and is entitled to conduct inspections of those sites.

Commerce published the Chemical Weapons Convention Regulations in December 1999 and called for submission of declarations by March 30, 2000. We have received a total of 3,076 declarations and export reports to date. Of the 138 sites which declared production, processing or consumption of a listed chemical controlled under the CWC, approximately 81 are subject to international inspection. In addition, 640 plant sites involved in the production of discrete organic chemicals are also subject to inspection, although only a few will actually be selected by the OPCW for such inspections.

As of May 2000, more than 230 sites have been inspected in the other 136 countries that have ratified the CWC. Since May, when the U.S. completed its implementation of the CWC, ten inspections have been conducted in this country. On average, we are receiving a notification of inspection approximately every other week. We anticipate a total of 18 inspections through December 2000, and up to 36 inspections in calendar year 2001.

Typically, the international inspection team consists of four inspectors, who divide into sub-teams to carry out specific tasks. Depending on the type of chemical (or chemicals) involved, these tasks may include a physical tour of the plant site, a comprehensive review of the records used to create the site's declaration, and negotiation of a draft facility agreement to guide the conduct of future inspections at that site. Inspectors attempt to demonstrate that the chemical in question has not been diverted for nefarious purposes. In order to do that, the inspection team generally conducts what is known as a "mass balance" analysis of the declared activity, tracing the chemical's path through the facility from receipt to production, processing or consumption, to shipment and inventory. This process is intended to "balance" the inputs of raw materials with the outputs of finished products. In addition, the inspectors have the right to request samples or formal interviews of personnel, although none have done so thus far. Once inspection activities are concluded, the inspection team completes a draft inspection report outlining their findings.

Inspectors have three primary goals: 1) to verify that the declarations submitted by the facility are accurate; 2) to evaluate the risk the facility could potentially pose to the object and purpose of the CWC (preventing CW development, production, etc.); and 3) to check for undeclared Schedule 1 chemicals, the most toxic type of chemical controlled under the CWC. If the inspectors are unable to accomplish these three objectives, they may recommend that the facility be subject to more frequent inspections or include a negative finding in their report. The sites we have worked with have been very cooperative, and have provided positive feedback concerning the conduct of these inspections. The inspection teams have been uniformly respectful, professional and competent. So far, all industry inspections have been completed successfully, and while a few significant issues have arisen, there have been no findings of non-compliance.

The Commerce Department's role in these inspections is to assist the U.S. facility being inspected to prepare for the inspection and to protect its confidential business information while also fulfilling U.S. obligations under the CWC agreement. The U.S. host team usually includes four Department of Commerce personnel, including the host team leader, as well as escorts from the Defense Threat Reduction Agency and a representative from the Federal Bureau of Investigation. A typical deployment for the host team lasts approximately 10 days. This includes work at the site prior to the arrival of the inspectors, the inspection itself, the preparation of the inspection team's post inspection report and the time spent escorting the inspectors until they depart the U.S.

Upon receipt of a notification that an inspection team is about to arrive, Commerce contacts the site and offers to immediately fly an advance team to their location to assist in preparations for the inspection. The work of the advance team can be critically important in

laying the groundwork for a successful inspection, particularly if no previous site assistance visit has been conducted at the facility.

The Commerce host team leader represents the U.S. in all dealings with the inspection team, but also acts as an intermediary with the facility representatives and ensures that their views are taken into account. Wherever possible, the host team will attempt to satisfy the inspection team's concerns by alternative means in order to avoid the disclosure of confidential business information. While the inspection teams occasionally attempt to probe for information beyond the bounds of their mandate, the host teams so far have had little difficulty keeping the inspections on track.

CWC inspections are relatively rigorous, so we have established a structure of support for industry at every step throughout the process. On our website (www.cwc.gov), we have posted comprehensive information on the CWC industry compliance requirements, including a number of outreach publications, declaration handbooks, the CWC Regulations, the text of the CWC and other resources. If companies are not sure whether a chemical they produce, process or consume falls under the provisions of the CWC Regulations, we provide them with commodity classifications upon request. This can be a difficult process, given the complexity of thresholds, mixture rules and other factors. We have responded to over 200 requests for commodity classifications this year.

We have conducted a total of ten seminars, including one just last month in Houston, to educate industry representatives on the declaration and inspection process. An eleventh seminar will be held late this year in Atlanta and will focus on inspections at facilities that produce, process or consume less toxic Schedule 3 and discrete organic chemicals with the broadest commercial uses. Inspections of these facilities have not yet begun in the US. We estimate over 400 industry representatives have attended one or more of these instructional seminars.

Facilities subject to inspection can request a site assistance visit, in which a Department of Commerce team goes to the facility to provide one-on-one assistance well before any inspection notification for the site has been received. The site assistance team walks the site through the elements of an inspection and tailors the information provided to the specific needs of the site. During these visits, the focus is on identifying CBI, creating a draft facility agreement, locating and assembling records that will make it easier for the inspectors to do their jobs, and preparing a pre-inspection briefing to introduce the inspectors to the facility. We have conducted site assistance visits at 10 facilities so far, and will continue to offer them to companies that request them to the extent that funds provided by the Congress and our personnel resources permit. We estimate that between 60 and 70 facilities subject to inspection could benefit from a site assistance visit, and we are committed to conducting as many as possible.

Inspections vary considerably from one facility to another. A large, complex facility engaged in multiple activities with multiple listed chemicals will necessarily be more complicated than, for example, a "close-out" inspection at a facility that has not been involved with scheduled chemicals for years. The inspection team has the right to conduct inspections for up to 96 hours at facilities producing Schedule 2 chemicals, regardless of the size or complexity of the facility. On a Schedule 1 inspection, which involves the most toxic chemicals, the inspection team has no time limit but generally restricts itself to 96 hours. In order to minimize the number of hours the inspection team spends at the site, we have worked closely with the OPCW and site personnel to expedite the inspection process. As a result, some recent inspections have been concluded in a shorter time. By utilizing site assistance visits and intensive advance team activities designed to anticipate inspector requests, we have been able to reduce the length of inspections and the burden upon industry.

Our preliminary data indicate that CWC inspection costs for each facility range from $15,000 to $63,000, depending in part on the number of personnel the site chooses to devote to the inspection and other factors. The average cost to the U.S. Government is approximately $50,000 per inspection. Such costs are to be expected given the labor-intensive nature of the inspection process, and are well within the estimates we provided to the Congress when the Convention was under consideration for ratification.

What lessons have we learned from the CWC inspections so far? In a nutshell, we can say, at least preliminarily, that the inspections to date demonstrate that it is possible to meet the requirements of a relatively rigorous international inspection regime at reasonable costs to both government and industry, and to manage the risks of revealing valuable company confidential business information. This lesson has to be considered preliminary because we have only begun the industry inspection process, and because how well the OPCW is able to preserve the confidentiality of the business information they obtain through the declarations and inspections, while satisfactory so far, remains to be proven in the long run.

The other lesson we have learned from these international inspections, however, is that this same degree of verification which we are attempting to achieve in the chemical field is unlikely to be achievable in the biological industry. A few comparisons will illustrate why.

First, confidential business information -- the intellectual property that biotech firms and their stockholders invest huge sums to develop -- is more pervasive at biological facilities than in the more mature chemical industry. Much information on chemicals and chemical formulae are published and in the public domain. In many chemical facilities, CBI is confined to a particular catalyst or production technique which is relatively discrete and simple to protect. That is less true for biological facilities, where far less information has been published and a company's

confidential information is often contained in the genetic material of living organisms which are themselves the final product or a key agent in production.

That being the case, indirect methods of inspection such as "mass balance" don't work, and process sampling is out of the question at biological facilities. When living organisms -- which grow, reproduce and may be "engineered" -- are involved in a process, it is not possible to determine what is being produced simply by knowing the ingredients and the resulting products. Even without knowing the specific process by which a particular microorganism was developed, anyone who obtained a sample of a proprietary organism from a facility or a formula in a lab book could reproduce unlimited quantities of a finished product that may have cost hundreds of millions to develop and embodies a company's entire intellectual property assets.

To further complicate matters, much of the equipment involved in biological weapons development is dual-use and also used in such common and widespread plants as breweries, bakeries, dairy product plants, and the like. This, combined with the fact that the U.S. has by far the largest number of biological facilities in the world, raises serious problems for establishing biological declaration "triggers" that will limit international visits to a manageable number of facilities and avoid a regime in which U.S. industry bears an excessive number of visits and inspections.

These problems are further complicated by the fact that biological agents are naturally occurring. Finding a chemical like sarin in a commercial plant means someone deliberately produced it, and since sarin has no legitimate commercial uses, its presence is a clear signature of CW activity. By contrast, you cannot make that assumption about biological agents like anthrax, which are found in the natural environment and may have legitimate uses, such as in the manufacture of vaccines. So the threat of false positives is real in biological settings, and is of

great concern to legitimate commercial producers whose integrity and reputation would be on the line during any type of on-site activity.

Finally, modern facilities are capable of sterilizing equipment in a matter of hours, completely eliminating any trace of organisms. The experience of UN Special Commission inspectors in Iraq indicates that on-site inspections cannot prove conclusively whether a site is involved in BW work or legitimate activities. That said, such on-site activities can provide useful information that can help contribute to our understanding of foreign BW programs.

The cost of future visits or investigations under a BWC Protocol is difficult to predict at this time. Imposing a CWC-style regime in the pharmaceutical and biotechnology fields would in all likelihood be considerably more expensive, given the serious CBI risks of such an exercise. On the other hand, more limited transparency visits would almost certainly cost less, because all access would be determined by the site and no CBI would be placed at risk. The declaration triggers included in any final Protocol will have a significant impact on the overall cost to industry. We estimate that there are only a few human vaccine producers in the United States, and at least 100 producers of vaccines for animals, all of which would almost certainly be subject to any future Protocol. Beyond that, it is unclear how many facilities will have a declaration requirement, since thresholds for fermenter size and other "triggers" that will determine the scope of any Protocol have not yet been agreed upon. The greatest impact on U.S. industry could come from the non-vaccine microbial production trigger, known as "Other Production Facilities." Depending on how it is constructed, this trigger could potentially capture a broad swathe of biotechnology firms, the vast majority of which are located in the United States.

We hope to get a better idea of the costs and benefits of visits and investigations by conducting a series of exercises mandated by Congress. With the assistance of PhRMA and the Biotechnology Industry Organization (BIO), we are seeking out potential industry sites and

observers to participate in such government exercises. We believe additional trial visits or inspections could help give both government and industry greater insight into how a BWC Protocol might be implemented.

These comparisons with the chemical industry do not mean that a worthwhile BWC Protocol is not possible. There are potential solutions for many of the challenges I have discussed. The number of site visits can be capped to prevent excessive inspection of U.S. facilities. Routine inspections like those conducted under the CWC can be replaced with general transparency visits strictly managed and controlled by the U.S. Government and company officials. Declaration triggers can be tailored to avoid affecting common industries such as fermented foods and beverages. Clarification visits designed to address anomalies in declarations, as well as challenge inspections to investigate possible offensive BW activities, both of which the U.S. supports, can be limited to those approved by a majority of the participating countries ("green light filter"). And, of course, export controls on biological agents, relevant equipment and technology must be maintained along with any international BW regime.

The U.S. position in the BWC negotiations has been carefully crafted to reflect these modifications of the CWC model, offering a regime that would provide transparency rather than verification of compliance with internationally agreed prohibitions on biological weapons. The U.S. position reflects not only the greater challenge posed by monitoring potential biological weapons activity, but also the concerns expressed by U.S. industry. We believe, however, that a regime that significantly enhances transparency in the biological area is a worthwhile goal, and we remain committed to achieving such a regime.

For its part, if authorized and funded to do so, the Commerce Department is prepared to undertake the same efforts to assist the biological industry that we are providing to the chemical industry. As I've mentioned before, the Commerce Department's role is to minimize the cost

and burden of inspections while maximizing the protection of confidential business information. That has been our goal throughout the implementation of the CWC, and I believe we have succeeded so far. Commerce will continue to ensure that industry concerns are taken into account and that protections for CBI are incorporated into any future BW regime. I am confident that industry will support a BWC Protocol if its concerns continue to be addressed in the negotiations.

Mr. Chairman, the stakes in these negotiations are high for the United States and for our economy. Our pharmaceutical and biotechnology industry is the world's leader. But competition is fierce and the levels of investment at risk are truly phenomenal. The loss of confidential business information in such an environment can be devastating. Industry support was crucial to ratification of the CWC, and it will be crucial for the ratification of a BWC Protocol.

We can best assure that support by building upon the cooperation we have received from industry in the CWC area and negotiating, as we are presently trying to do, a BWC regime that takes account of commercial realities and balances them with our need for enhanced arms control in this very challenging biological weapons arena.

Mr. SHAYS. Thank you, Mr. Majak.

Mr. Brock.

Mr. BROCK. Thank you very much, Chairman Shays. Good morning, Mr. Souder.

It's a pleasure to be here. You asked us some time ago to take a look at the actual experience of the companies that have gone through an inspection under the Chemical Weapons Convention. I think the first three witnesses have done a terrific job of laying out some of the differences between the industry and those that would participate in the Biological Weapons Convention and those that participate under the Chemical Weapons Convention. So I won't elaborate on that as we did in the statement.

Nevertheless, there are some key similarities. Any inspection is a burden. It's a burden on the company. The company is concerned about the release of proprietary information, the company is concerned about adverse publicity, and the company is concerned about how much the inspection is going to cost us.

The inspection process is a burden on the Government. The Government wants to protect the national interest, protect national security. So the Government participants at these inspections also have that burden. And finally, the inspection organization itself is under a burden, because it's obligated to see that the terms of the convention are being carried out.

So you have that mutual tension, you have those mutual concerns. And I think those are shared under both the Biological Weapons Convention and the Chemical Weapons Convention. Therefore, I think the experiences of the companies that have undergone the inspections to date do have some relevance. There are certainly critical differences, but there is some relevance and I'd like to briefly discuss that.

The first item you asked us to look at was the release of proprietary information. The Organization for the Prohibition of Chemical Weapons has a clearly set-out protocol for what it's doing to protect the information. The seven companies we went to all undertook various measures to protect proprietary information and proprietary processes. They screened information that was being sent forward to eliminate the possibility of proprietary information being inadvertently released, they shrouded equipment that would allow access to proprietary processes, they took any number of actions. And all seven were satisfied that they were able to adequately protect proprietary information, proprietary processes. This appeared not to be an issue. It was a cost, it was difficult to do, but nevertheless, it was achievable.

Second, in regard to that, all companies were very, very satisfied with the assistance that was provided by the Department of Commerce, and in a couple of instances with the Department of Defense, in working with them to make sure the proprietary information was protected. And that was a useful process in itself.

So to sum up proprietary information, it was the major concern of the seven companies we went to. And in all seven instances, they were satisfied that they were able to protect that information. And let me emphasize, this is the first seven. It's a very, very small subset of what the ultimate universe will be.

The second area was that of adverse publicity. No company wanted their neighbors and their stockholders or other involved parties to think that they were in fact producing weapons of mass destruction, that they were endangering the environment or they were in violation of an international treaty. They all had varying concerns. Most of the companies we went to wanted to limit public knowledge that an inspection was taking place. One company wanted to publicize that the inspection was taking place. No company thought that adverse publicity resulted from the inspection process.

And some of them did undertake some steps to limit the exposure of the inspectors to the community, things like that, that would limit the ability of outsiders to finding out the inspection process was taking place. Others didn't do that. It varied from company to company. But again, bottom line, not one company felt that any adverse publicity resulted from this. And that became less of a concern.

The last issue was on cost. The Department of Commerce, in developing an estimate of the cost burden, estimated that for a typical inspection, the cost would be about $54,000. We found that in the ones that reported the cost ranged from about $6,000 to $107,000.

I gave Mr. Majak a little boost a minute ago talking about their assistance during the inspection. This was an area that the companies all had concerns. The guidance on providing cost information was not very precise. The companies all undertook different methods and methodologies of reporting cost. These numbers are not auditable. And we have no certainty that they represent a true comparison.

Nevertheless, just eyeballing things, they don't seem out of line with what expected cost would be. But that's something that Commerce might want to consider in future operations as being a little bit more specific on the guidance of how costs should be provided.

The other observations I would like to make is that of the seven companies that we visited is that it's clear that the U.S. Government plays a key role in making these inspections work. As I pointed out a couple of times in my oral statement, the Department of Commerce and the Defense Department were instrumental in working with the companies to make sure that they didn't inadvertently release proprietary information, that they in fact provided material that was sufficient to ensure compliance with the convention, but did not go too far.

The Department of Commerce, in addition, held practice visits, numerous seminars where they were working with people, and in general, did a very responsible job of assuring that the inspections went very well. I think one of the things that we could look forward to in the future in terms of lessons learned, and particularly in terms of developing the inspection protocol under the Biological Weapons Convention is that hopefully the Department of Commerce and the Department of Defense are getting a lot of lessons learned out of this in terms of what can be done to alleviate the legitimate concerns of the pharmaceutical companies that would be subject to inspection.

That completes my oral summary, Mr. Chairman.

[The prepared statement of Mr. Brock follows:]

United States General Accounting Office

GAO

Testimony

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

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# ARMS CONTROL

# Experience of U.S. Industry With Chemical Weapons Convention Inspections

Statement of Jack L. Brock, Jr.
Managing Director, Acquisition and Sourcing Management

GAO/T-NSIAD-00-249

Mr. Chairman and Members of the Subcommittee:

I am pleased to participate in your hearing on the impact of proposed compliance regimes for the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (Biological Weapons Convention). These compliance regimes would affect a number of U.S. companies—mostly in the pharmaceutical industry but also may affect companies in the chemical, agricultural, and brewing industries. The pharmaceutical industry has expressed concern over the risk of compromising trade secrets, the potential cost of facility inspections, and the risk to corporate reputations should the public become aware that specific facilities are undergoing inspections related to biological weapons.

These concerns are similar to those expressed by companies affected by the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (Chemical Weapons Convention) prior to its ratification.[1] Accordingly, you asked us to assess the experience to date of these companies inspected under the Convention. Specifically, you asked us to (1) determine how companies protect proprietary information during inspections, (2) identify any adverse publicity for companies as a result of being inspected, and (3) identify the costs to companies of being inspected.

In brief, the experience of the first seven U.S. companies that have been inspected under the Chemical Weapons Convention showed that companies were generally able to protect proprietary information, in part because of certain provisions in the Convention and U.S. law. We also did not identify any instances in which a company was affected by adverse publicity resulting from inspections, even though companies varied in how much information was provided to the public concerning inspections. Lastly, these companies reported inspection-related costs to GAO ranging from $6,000 to $107,000. The large variation is partly attributable to inconsistencies in components of costs included in the total cost as well as differences in the facilities being inspected.

Nevertheless, I would like to caution that our ability to draw conclusions based on company experiences under the Chemical Weapons Convention is somewhat limited. While the Biological Weapons Convention protocols

[1] The Chemical Weapons Convention is the first arms control treaty to directly affect a substantial portion of U.S. industry—specifically, over 300 companies.

currently under negotiation bear some similarity to the Chemical Weapons Convention in terms of requiring companies to submit information and provide access to facilities, the level of detail for reporting and intrusiveness of inspections has yet to be finalized for the Biological Weapons Convention protocols.

## Background

The United States ratified the Chemical Weapons Convention in 1997. The Convention (1) prohibits the development, production, stockpiling, or use of chemical weapons, (2) requires the destruction of existing chemical weapons production facilities, as well as stockpiles of weapons, and (3) establishes an inspection regime to monitor the production, use, and transfer of chemicals that could be associated with chemical weapons.

The Chemical Weapons Convention established the Organization for the Prohibition of Chemical Weapons. As part of its charter, the Organization is responsible for the inspection of government and industrial facilities to ensure compliance with the Convention. The Organization's operations are funded by contributions from countries that have ratified the Convention. For 2001, the United States will provide the Organization with 25 percent of its funds, or approximately $5.6 million. The Organization employs over 200 inspectors from about 60 countries. Under the Convention, countries may reject specific individuals from conducting inspections on their territories. Exercising this right, the United States has blocked Cuban and Iranian nationals from participating in inspections of U.S. facilities.

The Chemical Weapons Convention, as implemented, requires companies to provide information and access to facilities based on the type and quantity of chemical a facility manufactures, uses, exports, or imports. Table 1 lists the categories of chemicals subject to the Convention.

**Table 1: Types of Chemicals Subject to the Chemical Weapons Convention**

| Type of chemical | Description | Example |
|---|---|---|
| Schedule 1 | Toxic chemicals that have little or no commercial use and were developed or used primarily for military purposes. | The nerve agent Sarin, which was used in the 1995 Tokyo subway attack. |
| Schedule 2 | Chemicals that can be used to produce chemical weapons, but have commercial uses and are not produced in large quantities. | The chemical thiodiglycol is used to manufacture ball-point pen ink and is also a precursor for mustard gas, which Iraq used against Iran in the Iran-Iraq War during the 1980s. |
| Schedule 3 | Chemicals that can be used to make chemical weapons, but also have significant commercial uses. | Phosphorus trichloride, which is used to make Sarin and insecticides. |
| Unscheduled discrete organic chemicals | Certain chemicals subject to the Convention that are not listed in a schedule and are used in a broad range of commercial products. | Propylene glycol, which is used to make antifreeze, and acetone, which is used in nail polish remover. |

Source: GAO summary of Commerce Department and other documents.

Under the Chemical Weapons Convention, companies must provide information annually on the quantity and location of specific types of chemicals to the Organization for the Prohibition of Chemical Weapons and must, when selected, submit to facility and record inspections by a team of international inspectors. The information and inspection requirements vary according to the risk of diversion of the chemical or facility to producing chemical weapons. For example, facilities that use, produce, or store Schedule 1 chemicals above a certain threshold can expect to be inspected at least annually and are subject to the most stringent reporting requirements. Other facilities may be inspected less frequently, based on the risk of diversion.

There are three types of inspections: initial, routine, and challenge. Initial and routine inspections verify the information provided to the international body as well as the absence of Schedule 1 chemicals at certain facilities. In the event that a signatory to the Chemical Weapons Convention is suspected of violating the Convention, a challenge inspection may take place. A challenge inspection may occur with very little notice and is not limited to those facilities that have submitted information to the Organization for the Prohibition of Chemical Weapons. To date, no challenge inspections have occurred.

## Similarities and Differences Are Likely to Exist Between the Chemical and Biological Weapons Conventions

There are likely to be broad similarities between the Chemical Weapons Convention and the Biological Weapons Convention protocols. Such similarities may include requiring companies to (1) submit information about facility operations to an international governing body, (2) provide international teams access to facilities, and (3) permit challenge inspections of facilities suspected of noncompliance. However, many of the details of the Biological Weapons Convention protocols have yet to be agreed upon and could result in significant differences between the two Conventions. For example, it is still unknown whether companies will be required to submit confidential business information to a governing body or what degree of access companies will be required to provide international teams under the Biological Weapons Convention protocols. The Chemical Weapons Convention requires companies to submit confidential business information to the Organization for the Prohibition of Chemical Weapons and requires companies to provide a level of access necessary to verify information provided to the Organization, including the review of production records and taking of samples for chemical analysis.

## Confidential Business Information Has Been Protected

Protecting confidential business information—that is, trade secrets or privileged commercial or financial information—has been an ongoing concern of U.S. companies in complying with the Chemical Weapons Convention. Similarly, protecting such information is a major concern for the pharmaceutical industry. For example, in the pharmaceutical industry, a sample of the product may be sufficient to reveal enough confidential business information for a competitor to gain an advantage. Nevertheless, we found that chemical companies believe that they have been able to protect their proprietary information, in part because of provisions within the Convention and U.S. law[2] and through extra measures taken by companies before and during inspections.

The Chemical Weapons Convention prohibits inspectors from disclosing confidential information they obtain during the course of their duties to unauthorized individuals. Furthermore, inspectors, like all employees of the Organization for the Prohibition of Chemical Weapons, are required to sign secrecy agreements that cover the period of their employment plus 5 years. If an allegation is made that an inspector or other Organization employee has violated the obligation to protect confidential information, the Organization must investigate. If the allegation is substantiated, the Organization can impose punitive and disciplinary measures. For serious breaches of confidentiality, the inspector's or other employee's immunity

[2] Chemical Weapons Convention Implementation Act of 1998 (22 USC 6701 *et seq.*).

may be waived by the Organization, which could result in that individual being subject to criminal or civil penalties in the affected country.

The U.S. company officials that we spoke with believe that they have been able to adequately protect confidential business information while satisfying the inspectors that they are in compliance with the Convention. In fact, the Convention itself affords companies some flexibility in taking measures to protect confidential business information, provided they can still demonstrate compliance. In particular, companies have taken specific steps to identify what constituted confidential business information prior to inspection and have removed or covered specific articles to prevent revealing such information. For example:

- In one case, a company removed barrels of chemicals that were not related to the inspection from the production area to a storage room that the inspectors would not have access to. In the view of company officials, identification of the chemicals in the barrels could have revealed confidential business information to the inspectors.
- A company covered sections of pipes in the production room that identified what chemicals were being used during the production process but were not related to the inspection.
- Another company covered up procedures manuals that contained sensitive information about production processes.
- Generally, companies maintained supervision of the inspectors by ensuring that they were continuously escorted while in the facility.

In other cases, companies have had to take extra measures to protect information while satisfying the needs of the inspectors and meeting the provisions of the Convention. For example, to protect production processes, one company ensured that all computer screens in the control room of the facility showed non-sensitive information before allowing inspectors into the room. Some companies have had to create summary sheets of production information for the inspectors because the raw data would reveal confidential business information.

In addition, U.S. implementing legislation provides for the protection of confidential business information and severe penalties for violations on the part of any current or former U.S. government employee. Section 404 of the Chemical Weapons Convention Implementation Act of 1998 exempts confidential business information from public release under the Freedom of Information Act, but permits disclosure to the Organization for the Prohibition of Chemical Weapons, congressional committees or

subcommittees of jurisdiction, and law enforcement agencies under special circumstances. The law also provides for fines and imprisonment in the event of willful disclosure of confidential business information.

Federal agencies also provide assistance to help companies that are inspected protect confidential business information. The Commerce Department has sponsored seminars to explain the requirements of U.S. regulations implementing the Chemical Weapons Convention and to suggest how to protect confidential business information. Commerce and other agencies also provide site assistance visits to help companies prepare for inspections. Moreover, during inspections, Commerce and Defense Department staff escort the inspectors at all times to prevent unauthorized access to facilities and information and a Federal Bureau of Investigation official is on site for counterintelligence purposes.

## No Adverse Publicity From Inspections Reported

Many companies have been concerned about negative public reaction to knowledge that a company has been inspected under the Chemical Weapons Convention. For example, neighboring communities might be alarmed that a chemical produced nearby could be used to create a weapon. As one industry official said, the worst case scenario would be a minor technical error resulting in a headline stating that the company failed a chemical weapons inspection. To date, however, U.S. companies we spoke with have indicated that there has been no adverse publicity related to the inspections under the Chemical Weapons Convention.

To prevent adverse public reaction, chemical companies have chosen to either (1) not publicize the fact that their facility is subject to inspection or (2) initiate a dialogue with surrounding communities about inspections. In choosing the first approach, one company stated that the local community in the past has objected to the presence of the facility near houses, and that it did not want any more negative publicity. In opting to inform the public about impending inspections, one company said that hiding the information would be more damaging than addressing the concerns of the community. Federal agencies have accommodated company decisions in both approaches.

## Cost of Inspections Vary

We obtained cost data from the first seven companies to be inspected and found that they identified inspection costs ranging from $6,000 to $107,000. We were not able to audit these costs. However, we found that factors affecting this variation include the types of costs companies are reporting, how they calculate those costs, and differences in the facilities inspected.

The Chemical Weapons Convention Implementation Act of 1998 requires the President to submit an annual report to the Congress on inspections made under the Convention. The report must include such information as the number of inspections conducted in the United States during the preceding year, the cost to the United States for each inspection, and the total cost borne by U.S. industry in the course of the inspections. In implementing this Act, Commerce regulations require facilities that have undergone an inspection to report total cost related to the inspection to the Bureau of Export Administration within 90 days of the inspection. Although the regulation states that the reports should identify categories of costs if possible, Commerce has reiterated that the only mandatory reporting is for total cost. Four companies told us that they have submitted inspection-related cost data to the Commerce Department.[3]

One reason for variances and inconsistencies in costs being reported is that Commerce did not provide detailed guidance to companies concerning what types of costs should be included or how to calculate inspection-related costs, which may limit the usefulness of the cost data. As a result, companies are including different types of costs as they prepare cost data to submit to Commerce. For example, one company included all costs related to compliance with Commerce's regulations on the Chemical Weapons Convention, including the costs of preparing the initial report to the Organization for the Prohibition of Chemical Weapons. The company also included the cost of briefing headquarters executives on the results of the inspection. Another company included costs related to an internal practice inspection prior to receiving notification of the actual inspection. Other companies limited their reported costs to those related to the inspection from the time that Commerce notified the facility of the impending inspection until the inspectors departed. In addition, companies varied in the other costs identified. For example, two companies identified only labor and travel costs, whereas other companies included the use of conference rooms, faxes, photocopiers, and delivery services.

The regulation also did not explain how companies should calculate costs. For example, all companies included labor costs, but calculated them differently. Some companies applied the number of hours employees spent on inspection-related tasks to actual wages, while others used an average or standard hourly rate. Further, in calculating labor rates, most companies included the cost of employee benefits in addition to salaries

[3] Of the seven companies we spoke with, the three who have yet to report costs to Commerce are still within the 90-day period.

while one did not. Some companies tried to directly track costs, while others estimated costs for reporting purposes. Two companies established a cost code for the inspection in order to capture costs. Another company said that creating a separate cost code for inspection-related activities would have been an unnecessary cost because of the infrequent nature of the inspections.

To some degree, the variances in the costs that facilities incur as a result of these inspections may be attributable to differences among the facilities themselves and how the facilities prepared for inspections. For example, a company that is involved in the production and consumption of multiple chemicals subject to inspection may require more time and effort to prepare for the inspection than a company that only uses one chemical subject to inspection. For safety reasons, one company decided to suspend its operations during the inspection, which resulted in lost business that was estimated and included as a cost. Other companies did not suspend operations. Two companies hired outside legal counsel to assist in the preparation and conduct of the inspection, while other companies relied on in-house legal services. Also, one company provided training to facility personnel who could come in contact with inspectors to prepare them for the inspection, which was included as a cost incurred by that company.

In addition, the costs reported by the companies may not be representative for the entire industry. As of September 1, 2000, only nine U.S. industry facilities had been inspected under the Chemical Weapons Convention. The first inspection occurred in May 2000. The facilities that have been inspected to date use or produce Schedule 1 or Schedule 2 chemicals. As these chemicals have the highest risk and the most stringent inspections, the experience of these facilities may not be applicable to facilities with Schedule 3 and unscheduled discrete organic chemicals. For example, the Chemical Weapons Convention permits inspections related to Schedule 2 chemicals to last as long as 96 hours (4 days), but limits the inspections related to Schedule 3 chemicals to 24 hours. As a result, the cost of hosting a Schedule 3 or unscheduled discrete organic chemical inspection will likely be less. The frequency of inspections may also have an impact on future costs. For example, all Schedule 1 facilities are subject to frequent inspections and therefore may experience cost decreases as they become more familiar with preparing and hosting inspections. However, other facilities will be inspected less frequently and therefore may not experience such cost decreases.

It should be noted that in addition to the costs borne by the companies, the U.S. government and the Convention's governing body also incur costs.

For example, for the seven inspections we reviewed, the U.S. government paid the salaries and travel costs for federal agency personnel who went to facilities to help companies prepare for inspections and to escort the inspectors. The cost of inspectors' salaries, transportation to the United States, and accommodations during the inspection are paid by the Convention's governing body, which is supported by member states.

In conclusion, though there are parallels between the two conventions, the relevance of our findings will largely depend on the specifics that are agreed upon under the Biological Weapons Convention protocols. This is particularly so with regard to the risk to confidential business information since issues such as the level of detail of reporting and the level of intrusiveness of proposed inspections have yet to be resolved. The risk to corporate reputations from adverse publicity, on the other hand, is likely to be similar to that experienced by chemical companies under the Chemical Weapons Convention. Lastly, while the types of inspection costs will most likely be similar to those incurred by the chemical industry under the Chemical Weapons Convention, the costs may well be different because of differences between the companies. Further, the usefulness of reporting costs will depend on the consistency and completeness of the data reported.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions you or the other Subcommittee Members may have. Major contributors to this testimony include Katherine V. Schinasi, Thomas J. Denomme, Johana R. Ayers, Cristina Chaplain, Delores Cohen, Dianne D. Guensberg, Paula J. Haurilesko, Stephanie J. May, David Merrill, and William T. Woods.

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Mr. SHAYS. Thank you very much.

Mr. Souder has to go back to another two hearings, and will start off the questions.

Mr. SOUDER. One of them is a markup on my bill at 11. So I didn't make an opening statement, I'd like to make a couple of comments, just a couple of questions. One is, I thank you for your efforts. I think this is a lot, in my case, like many Americans, you just kind of hope this stuff gets done. When you start to learn the details, it's a lot like watching the sausage being made. Because as you've raised different questions, you realize the complicated nature, for example, in biological, I hadn't thought out the differences.

When I was over in the Middle East with this subcommittee a number of years ago, and the inspectors had just been kicked out of Iraq and were looking at going back in the next morning, we had the opportunity to talk to a number of them that night on looking predominantly at chemical weapons. And it was incredibly difficult, as they talked about multiple different places where the precursors may come in. They claimed they were doing animal research and all this kind of thing, trying to determine even in something easier to track in a country that's highly suspected, to say the least. And yet it was very difficult.

The things you've raised with biological are even more complex. A couple of general comments, one is that I think there's an increasing discouragement in America, particularly after the nuclear secrets question that didn't build trust in industry that we know how to protect things, if we get that confidence.

Because if there wasn't espionage and it was incompetence, that isn't encouraging on proprietary information, whether disks are left alone and people walk away, we all know how hard it is, in employees, we all know, to get people who are very focused and Government pay isn't the highest place right now. It is something that we have to constantly work at. And I'm pleased to hear you say that that's a stress. But it must be a stress. Because right now, if there's a moment when industry is going to be distrustful, it's right now, in these areas. Because we haven't been this shaken about our capacity to protect our utmost secrets, as I would argue we are at this point, maybe other than during the early development and early results off the early nuclear arms race.

A second thing is that as somebody who comes from a small business perspective and has been very defensive of trying to come up with not under 25 employees, not under 50 employees, not under 100 employees, certain sales limits, I realize that one impact is that as Government has proliferated regulations, has been this whole concept of breaking into subdivisions or getting in what you call the other categories.

Clearly your example here potentially in breweries is interesting, because we've seen the whole microbrewery phenomena and we don't want to inadvertently trigger that which could cause tremendous complications as we try to address other pharmaceutical related questions, for example, in Medicare and in health care, and try to get generic drugs under question, try to push research in AIDS, and then find out that in the chemical-biological area, we've put additional costs on.

And one brief comment on the costs, you know, if it's $6,120, one variation there is, did they assign an intern to walk with you or the president of the company? How do you factor in what the different levels of the corporation, their managers and the time they're spending thinking about what they're going to do. If we actually put a time value of money on the corporate executive investments, these costs would soar. There's direct and indirect.

I'm pleased you're working with industry. It's encouraging to me that you're trying to address the question.

And one last thing is, do you have any reason to believe that in chemical and biological proliferation that anywhere in the world it would actually be facilitated by somebody who was above-board enough that you could actually do an investigation, even within a country like the United States? Or is this in effect more like what I think was in Dr. Koch's testimony, almost like a good housekeeping seal that in fact assures the world potentially on liability concerns that these companies are part of it?

In other words, is there really a reason to believe that in any country, the people you're investigating and who you can actually test these things on would be somebody who would be providing it? Or even if it was that company, that it wouldn't be a rump sector in it who the corporation wouldn't even know? Ambassador, would you like to take that?

Ambassador MAHLEY. Thank you, Mr. Souder. I'll take that last question, as a matter of fact.

I think the answer is also very complex. But let me try to sort through it very quickly. First of all, no. Given that all the people who would be in this protocol are also people that are parties to the convention, there would be no one who would be overtly or openly conducting biological weapons activity, which they would then announce as part of that inspection.

No. 2, they would even necessarily be doing it at some place that would be a declared facility, that is, some place that was doing something as a legitimate activity which made them part of a declaration. That's why we are trying very hard, in the protocol that we're trying to negotiate, at least, to make sure investigations are available. Because those are challenges. If we have indications that some facility is doing something illicit, that we can go investigate that, even if it is not a declared facility. But it has to be on the basis that we have some suspicion there's something illicit going on there.

Second, in the question of clarification, there are such things—clarification visits that are a part of one of the technical aspects, to clarify declarations. One of the clarifications that we demand be incorporated is the clarification that says if there was an activity that should have been declared going on at an installation or facility that has not been declared, we get to go ask that question, or rather we get to have the international staff go ask that question.

So that if they've tried to conduct that kind of activity and not declare it internationally, we still have the right to go in and say, what's going on here. Now, that takes care of, I think, as best you can, the question where somebody's trying to outright hide it and not say anything about it.

The other question is whether or not there's somebody doing something that is covert and illicit underneath the cover of other activities that are going on. Certainly we would not expect them to come out and tell us that as we went into an inspection, or as the international staff went into an inspection. But one of the things that we're trying to do in terms of the experience we're building up, and in terms, frankly, of some of the experience that we have from both the United Nations Special Commission and some of the experience we have in terms of asking questions, for example, in the former Soviet Union as a part of a process that we undertook several years ago, is to find out what kind of things might happen if someone isn't telling the truth.

There is no guarantee of this. I'm not trying to say that this is a guarantee, we'll catch them every time. But I can tell you from personal experience of having been on some of these kinds of inspections, that when you have people trying to put up cover stories, having folks onsite asking questions increases the likelihood that somebody's going to make an inadvertent statement; increases the likelihood that they're going to say something which is not logically consistent; increase the opportunity to make your own observations about whether or not the conditions you see are consistent with the story you're being told.

All of those, we believe, are valuable assets in terms of trying to make a determination about whether or not there is an illicit activity going on. Again, I want to emphasize, it's not foolproof. We're not trying to tell you that we can catch it all. But certainly it is the case that we do not expect people to come out openly and tell us that they're doing biological weapons.

Mr. SOUDER. What seems to be the case, and I'm trying to sort through, this is a pattern we have in all sorts of investigations, all sorts of programs in the Government, I've worked very directly with the illegal narcotics, for example, ephedrine producers in Mexico, if you see this huge surge, it leads you to ask certain questions, even if it's a legitimate use coming in. You wouldn't have apparent that legitimate a use for that much, because it was a change.

But one of the struggles we have is how much, for example, in the anti-drug program in schools, how much is spent reaching kids who aren't as highly at risk versus how much is spent at risk. And in your comments there, it's difficult for me to sort out how much of our investigation time is being spent on making sure our major companies are clean when we don't necessarily suspect anything versus how much is spent on looking for these unusual activities that would be a trigger, to look at that. And as part of that, because we need to show that if we just look at triggers, that would add additional suspicion and marks on those companies, and we need to have kind of like everybody's doing this.

But in the prioritization of, and limited funding, how much of this is being targeted at least at some element of questioning versus kind of routine inspections of places that have too many dollars at risk, really, to necessarily mess with this right now?

Ambassador MAHLEY. That's a very good question. And again, the answer is going to be a little indirect, but I'll try to make it as brief as I can. First of all, remember that this is not a case of

what we're going to be inspecting. This is a case of what an international organization is going to be inspecting.

Second, in terms of what are you going to be doing in terms of routine activities, one of the things the United States has made a very strong point about in these negotiations is that we will not permit this to have a disproportionate burden on the United States. We are not going to accept a provision, for example, in which the quantity of declared facilities is going to be the determinant of how frequently a routine, onsite activity takes place.

Because we're going to have more facilities to do whatever kind of activities it is that we describe as being declarable activities under any protocol that anybody else is going to have. So therefore, if you did a straight proportion, most of the inspection time would be spent in the United States. As I have said in Geneva many times, we're not the problem.

Therefore, that's one in which we have set up ways in which we spread, by the code word of equitable geographic distribution, which means you try to make sure this routinized activity, goes to places where we might have some concerns as well as to coming to places in the United States.

The second part, though, is that there are two kinds of activities. There's the routinized activity, clarification visit or a transparency visit or a familiarization visit, whatever it may be. Then there's also the investigation. The investigation, which is the most rigorous of the onsite activities visualized, is very carefully focused. It does not occur on a routine basis. It only occurs in response to an allegation that there may be a concern at a particular location.

And so therefore, it does not happen at some place except where a country has made an allegation of some kind of a violation.

Mr. SOUDER. I thank you. In looking at something like IRS, one's an audit, one is a suspect audit, and one is a kind of a random audit that you come through. But random audits put a lot of pressure on, too. I appreciate your response and we'll try to do some followup on bills up in committee.

Mr. SHAYS. I thank all of you. I would like to just begin my questioning by, Ambassador, you describing, and Dr. Koch, if you would like to, what the problem is in terms of just the threat of biological agents to the world. You didn't speak to it in your testimony. I'd just like the committee to have a record of it.

Ambassador MAHLEY. Thank you. I would like to start out and then I'll turn it over to Dr. Koch to supplement. The problem of threat, of biological agents in the world, is in my view, and I think I can say pretty much the Government's view, because I think it's consistent with what other agencies, even intelligence agencies, believe. It is something that could be done as a covert threat on a very small scale, and still be very significant. It is something that could be done, frankly, relatively cheaply.

It is something which could be done inherently within the infrastructure that any country has available to it for very legitimate purposes. As I think all of us have said in our opening testimony, these are truly dual purpose capabilities. You can make a vaccine 1 day and a weapon the next in the very same fermenter with the very same building blocks of material. Anthrax is a classic example of that.

So the threat is ubiquitous in the sense that it goes every place you can go. It is, we fear, in our assessment, increasingly in some states of concern a means of trying to achieve a weapons of mass destruction capability which may be more covertly available, easier to obtain. And the number of countries that seem to be interested in this seems to be growing. So it becomes increasingly attractive.

The other part of it is that there's also a real threat out there, we believe, from non-government actors, and that is the terrorist activity. And frankly, we do also believe that the protocol could be useful in terms of counter-terrorism, in the sense that one of the requirements we're going to put in it is the requirement for domestic legislation outlawing such things, which may actually have the value, at least in countries that are not countries of concern, of their creating an infrastructure domestically which will make it more difficult for a terrorist operation to use them as a base of operations.

So I don't know if that's answered your question or not, but that's sort of the question about the threat as we kind of see it out there in the world. And I'll ask Susan if she'd like to supplement that.

Dr. KOCH. I would just endorse what Ambassador Mahley has said, that the threat is real, the threat is growing, the threat is very difficult to detect for all the reasons that Ambassador Mahley described. The concern with the potential impact of any use of biological weapons, on whatever scale, against our forces and our population is very real.

Mr. SHAYS. Well, just to respond, I think both of you have, in a very concise way, described a gigantic threat. I wouldn't say this as something to be sensational, but how would we know or not know the West Nile virus was introduced by accident or introduced by a terrorist? How would we know that?

Ambassador MAHLEY. Mr. Chairman, I think to get the best answer on that, you probably ought to have a more technical briefing from people who do this for a living, that do epidemiology, like people from the CDC. But we have had a number of discussions with those people about this question, so I'll try to do the best I can as a layman to try to convey some of their answers.

Mr. SHAYS. Your answer will probably be more understandable.

Ambassador MAHLEY. I won't guarantee that. I never guarantee my answers are understandable.

There are a number of things that you can look at from an epidemiological standpoint that would stand out as to whether or not an incident was something that looked like it was natural or looked like it was abnormal. We're wrestling with some of those in the negotiation, for example, because one of the things that we want to have is an investigation of unusual or suspicious outbreak of disease. To do that, you have to have some idea of what would constitute a suspicious outbreak of disease.

For example, if you have a single source in terms of tracing back the outbreak, that's one real clue about whether or not you may have a suspicious outbreak. Because if you've got multiple source startup at the same time, then that probably means that there was more than an infected mosquito that got off an airplane. That would mean that somebody was spreading for example West Nile

virus around in several locations or by several vectors simultaneously.

The second thing is that you have to look at whether or not there are some indications that would indicate the distribution of the outbreak, as in a pattern which might occur as a natural function, or whether it is a pattern that might occur as an artificially induced function. Again, the interesting part of the Sverdlovsk investigation, for example, of the anthrax outbreak in 1979 in Sverdlovsk, now Yekatrinberg, really got down to the point of being able to detect that it all had to have occurred on a single afternoon, and that the afternoon that it occurred was an afternoon in which the wind direction was different than it had been for other days. And lo and behold, that happened to fit the pattern of outbreak.

And as a matter of fact, insofar as you could look at outbreak that was over a long range, in this case a couple of hundred kilometers, you would get this outbreak which looked like it would have had a day or two for the wind to begin to carry it for the total of 200 kilometers downrange. So there again, those are the kinds of things that you can look at.

CDC looks at things very carefully with respect to such elements, I think that you'll find that they've done a very good job. I'll point to one example, we think there was an example in the United States of a cult attempting to use biological weapons in the United States, or trying to test them up in Oregon in the 1980's, with salmonella. And CDC came up with a conclusion on that that said it appeared that you had two simultaneous outbreaks on the same day which were in different locations and which had different sources. So therefore it would not have been a single infection source, and that was what put them onto the thesis it was probably an artificially introduced disease.

I can't really give you a technical explanation of all the ways to do that. But there certainly are a lot of ways which we spent a lot of energy already today on trying to make sure we have that kind of assessment the best we can.

Can we do it uniquely to say, absolutely, the West Nile outbreak was not a mistake or an accident some place, but it was a natural occurrence? I don't think any of my colleagues in the scientific community would come up and try to give you a guarantee of that. We'd give you our best scientific evidence.

Mr. SHAYS. Would anyone else like to respond?

Let me just explain, in a circumstance like this, which I frankly don't mind one bit, with one questioner, we have the flexibility to have some interaction. So if I direct a question to any one of you, I'm happy to have any of you respond.

But I still am going to kind of go in the areas that Ambassador Mahley and Dr. Koch are more involved in. I think you both gave me a pretty tremendous answer on what the threat is. The irony is, not an irony, but the fact is that if the West Nile virus was in fact a terrorist induced or induced by a country, this hearing would have 50 cameras and there would be a line a mile long.

And yet what we're talking about is very real. And the likelihood that some day we'll be faced with that is very real. So I consider this an extraordinarily important hearing.

The bottom line to your answer, Ambassador, is that while I don't suspect, for instance, that it was terrorist induced, we don't know. But we have indicators that would suggest that it wasn't. And you're trying to develop, others are trying to develop as well, and you're trying to make sure we recognize the need to step in in places around the world where you see this kind of episode.

This committee, or let me put it this way. I used to chair the Committee on Human Resources that oversaw all of HHS, CDC, and National Institutes of Health. Basically my staff came from that committee. So this is an area that just astounded me, because I thought, here we're trying to protect from nuclear and threats by armies, and yet the biggest threat can be by a virus, the biggest threat can be a health threat. And I realize more than I ever have the importance of the World Health Organization and the effort that the U.N. clearly has in protecting world health.

So we know it's a gigantic threat, we know it can be done on a small scale, we know it can be done cheaply. We know a vaccine 1 day can become a weapon the next. We know that the number of countries are growing, we know that they're becoming involved in biological weaponry, we know that terrorists are flirting with this as well. So we know the threat is real, we know it's growing and we know it's difficult to detect.

Which gets me to the issue of how do we deal with it. Obviously that's the issue we have. In my statement, I said to what extent is the BWC verifiable. And I made the same point that you were making. I guess my problem is, in my heart of hearts, I don't think it's verifiable. And I almost think, Ambassador, I'm tempted to think that you are a Don Quixote.

So tell me why this is a worthwhile effort. Let me just make a point. In your statement, you said, on page 8, and I'm reading, let me read the whole statement. I don't think that you read this part of your statement. First of all, this is not an issue of verification. As you know, the United States has substantive requirements for attributing effective verifiability to a treaty. It involves being able to make a judgment of high confidence in detecting a violation before it can become a militarily significant threat.

I have already noted that a small program can become a threat. Likewise, the inherent "cover" for an illicit program in legitimate activity makes differentiation much more imprecise. And this is the quote: The United States has never, therefore, judged that the protocol would produce what is to us an effectively verifiable BWC.

Can you explain that?

Ambassador MAHLEY. Yes. In order to have an effectively verifiable convention, we would have to be able to testify with honesty that we were able to meet those kind of standards about early detection of any program before it could become a militarily significant threat. Now, the obstacles to that are enormous. First of all, very small programs could be militarily significant. Second of all, they are enormously flexible in terms of their appearance and disappearance.

Third, as I think the Soviet Union even learned after its program in the 1960's, a priori stockpiling of biological weapons is not something that's necessary, because you don't need that many of them to proceed with implementation. So therefore, having large stock-

piles of weapons sitting around for a long period of time to detect before you're ready to use them is not necessarily one of the things that will happen in a program.

For all these reasons, we simply, and again, I'm basing this on my colleagues in the intelligence community's capabilities as well, the United States simply does not assess that we can gain that kind of confidence and that kind of information. And we have therefore resisted calling this a verification protocol or an attempt to make the Biological Weapons Convention verifiable, because we think that would indeed be an impossible goal, and it's certainly not something we're prepared to try to argue in terms of the U.S. Congress for advice and consent for ratification would be something we've achieved.

Now, that, however, all is preliminary to the question that you've actually asked, and that is, therefore, why are we going about this negotiation and what is the value that we can get from it. I think the answer to that has got to be again one of comparative costs and benefits. Certainly if there's a real risk to U.S. national security or a real risk to serious U.S. propriety information, then those would be very difficulty obstacles to overcome.

As I think Dr. Koch and Mr. Majak have testified today, and certainly as I believe on the basis of the work we've done, the U.S. negotiating position and what we're after in this protocol will not put those kinds of national security or proprietary information values at risk in any extensive forum, and the cost and burden for the United States will not be excessive.

If one can achieve that, and at the same time increase the flow of information in some of these areas, then the question you have to ask yourself is, is that a net benefit to the United States. Is it of some value in our global effort to try to prevent biological weapons proliferation. On balance, the net assessment is yes.

Now, why is that the case? It is the case because again, as I said to Mr. Souder, we don't expect that people are going to declare that they're doing biological weapons programs. We do expect to be able to set down some definable and clear categories of activity which we hope are going to be the most relevant to the biological weapons convention objectives. That's what we're after.

There is another complex problem as a side light, because what is relevant changes as biotechnology changes. How large a fermenter, for example, is relevant? A country would declare every place that's got a fermenter of such a size or larger. The criterion becomes enormously fungible, as you can do more and more things in smaller and smaller fermenters.

Nonetheless, if you set down some clear and distinct activities to declare that means you declare some activities and some facilities in your country. Those facilities, if somebody were stupid, could be the places where they could take advantage of the infrastructure to use the dual capability to run a covert offensive program.

If they're going to do it that way, then there is always, I think, the chance that if you go routinely onsite to those kinds of activities there will be discrepancy which is observable which will, while it isn't a smoking gun, provide you with an opportunity to focus your own national assets the attention of the world on that instal-

lation and that activity. And therefore, that's not a path which the proliferator would find to be more profitable or easier to follow.

Second, by having categories of things which should be declared, then you can raise your eyebrows with great interest if you discover by other means that those same activities are going on at different locations which have not been declared. You have to ask yourself the question, why did the owning state not declare those activities at those locations. So you ask for clarification.

It's always possible there was a pure oversight, in which case you will probably find there installation in question suddenly appears on the declared list. Then you can then either pay more attention to it in succeeding years or not.

However, you always have the challenge capability to go to any place that you think some kind of activity which might be of dubious nature is going on. I don't want to try to leave you with the impression that we believe we're going to find a smoking gun, or we're going to walk in or somebody's going to say, oops, let me get rid of these bombs right quick before we go on with the inspection.

But challenge is a deterrent threat. Now, is it a deterrent threat that we believe is capable of precluding someone from undertaking covert activity? No. But it is a deterrent threat which makes it more complicated and more expensive for them to do so.

And in trying to create that kind of a complication, then it appears to us that we do have the chance of downgrading the seemingly growing attractiveness of a biological weapons program as a means of creating a weapons of mass destruction capability. If you make it more complicatedc and expensive to go underground because a proliferator must make sure that a program does not look obvious and therefore might cause somebody to ask questions, then there is suddenly a greater complication to any national security equation for creating a weapons of mass destruction capability for a country.

And that is something which we believe will add to our other national efforts in terms of trying to counter proliferation. Now, when I say will "add to our national efforts," that also becomes then one very important element. And that is that we cannot allow getting this very modest international capability in place to detract from, to deflect or interfere with our own very vigorous national program to try to reach those same objectives. That's one of the reasons why, for example, we will not tolerate any interference with our ability to make our own national decisions about proliferation questions.

Mr. SHAYS. In one word, can you summarize what you said, or in one sentence? [Laughter.]

Ambassador MAHLEY. I'll try very much, sir.

Mr. SHAYS. I'm not trying to be cute. I think I want to tell you what I'd summarize, but I want you to go first.

Ambassador MAHLEY. The protocol should provide a supplement to the efforts internationally to stem biological weapons proliferation by complicating the life of a potential proliferator. Thank you.

Mr. SHAYS. My summation would be, from hearing you say it, it won't do much, but it's better than nothing. And you explained why it's better than nothing.

Will the record note that his head went up and down, which means that he concurs with my statement? [Laughter.]

I seem to be focused mostly with you, Ambassador. But let me just tell you the next question I'd like you to answer, and then I'm going to ask you, Mr. Brock, to respond. You said in your spoken statement that CWC lessons, some are good, some are dubious and some are not at all. I don't know what not at all means. Good, dubious and no lessons at all. You did say that. And if you would give me examples of each, and then I'd like you, Mr. Brock, to respond to it.

Because Mr. Brock, let me be clear. We asked you basically to look at CWC and see if we could draw some parallels in terms of costs to business.

And Mr. Majak, I'm basically going to be coming to you to just understand one, why the pharmaceutical industry may have chosen not to be here, and then to have you explain to me how you sort this whole issue out, again, in briefer terms, of inspection.

And Dr. Koch, you're looking at inspection from the standpoint of—you're looking at it, Mr. Majak, from proprietary interests, I think, you're looking at it from a national interest. I'd love you to be able to, I'm going to be coming to you to have you explain to me, we don't make biological agents. So explain to me what we're protecting.

So Ambassador, I'm going to go to you, and then I'm going to have you, Mr. Brock. I'm just trying to make sure that all four of you feel engaged here, so you don't fall asleep on me. I'm engaged.

Examples of good, dubious and there's no comparison. Not relevant.

Ambassador MAHLEY. One of the good things I think we got out of the Chemical Weapons Convention that we're trying to apply is the principle of managed access. We devised managed access as a part of the Chemical Weapons Convention negotiations. Managed access must have a case by case, onsite negotiated approach to being able to protect sensitive information not relevant to the object of the inspection. But nonetheless, you can satisfy the purpose of the investigation itself.

We have to protect information on a case by case basis. You can't write in the treaty text that you shall be able to do the following things for protection. You can give an exemplar list, which we do. Nonetheless, the answer to that is no, you don't want to try to make that all the things you can do. So you have to be able to look at protectioin on a case by case basis.

The principle, I think, very cogently applies in the biological area as well as the chemical area. And certainly we are enshrining that very same principle in the negotiations in the biological convention.

What is dubious? In the Chemical Weapons Convention, you have a schedule 1 and schedule 2 chemical list. Now, the schedule 1 and schedule 2 chemical list are pretty much in the schedule 1, all the chemicals that are known to be chemical weapons. There may be some speculation about generations of agents, but nonetheless, these are ones which are either chemical weapons or immediate precursors and have no commercial value. So therefore, you subject all their manufacturers to certain constraints.

Then you have schedule 2 chemicals, and that's a definite list of chemicals, and that's what all the people who do those, in terms of production and consumption, are subject to category 2 restrictions.

To try to make a list of biological entities which would have the same relevance to biological weapons would be problematic at best and damaging at worst. Because given the state of biotechnology, given the question about what kind of objective you have for a biological weapons program, for example, if you want a military application of biological weapons, one of the things that we learned when we did our offensive biological weapons program is that you wanted to make sure that anything you had as an agent was not contagious. Because you wanted to make sure that it was applied only to a specific area for military operations and did not then run rampant throughout the country in terms of that kind of a purpose.

If you're a terrorist, you may not care about that. So therefore, a completely different list of pathogens would be things that you would look at as high priority agents. So therefore, trying to make a list such as you did with the Chemical Weapons Convention is very dubious.

What doesn't apply at all? Again, once you had category 1 and category 2 chemicals in the Chemical Weapons Convention, you were therefore able to try to categorize all of those facilities that dealt with those two categories of chemicals and subject them to routine onsite activity. And that would pretty much take you through the entire list of capabilities in a country, commercial or otherwise, in which you had the kind of high corrosion resistant, high containment chemical reaction capability which would be most reasonably diverted into a chemical weapons program if you wanted to do so.

There simply is no such equivalent category of equipment or of capability in terms of biological weapons. Some, for example, argue that the most dangerous pathogens have to be dealt with with maximum biological containment, what we call BL4. Well, when the United States, again, had an offensive biological program back in the 1960's. We worked anthrax on the bench by simply having air containment around the entire facility and good inoculations of all the people who were actually working on the program.

So therefore we didn't use maximum biological containment in that operation. We had no accidents and we had no casualties from it. And so one could do that, and certainly one could do that in a covert program if you were prepared to take a little bit of a risk with your work force, even if you didn't have vaccinations.

So the idea of having some sort of a categorization such as that is an example from the Chemical Weapons Convention that would be very dangerous to apply in the biological weapons area.

Mr. SHAYS. Mr. Brock.

Mr. BROCK. A couple of points, Mr. Chairman. I think the inspections at the chemical companies demonstrated that in fact you can protect the interests of the companies during an inspection. And the available material that I've read and that has been provided to us indicates that the industry is segmented in such a fact that these inspections do give you a level of assurance that may not be present in a pharmaceutical interest.

And I was really intrigued by your line of questioning you just went through when you were talking about what level of assurance do we have that we if we do the biological inspections that in fact we're comfortable with our ability to protect ourselves. And I think there's a real parallel between that and some of the things that we're looking at in GAO right now. We're looking at cyberwarfare and cyberterrorism, where the National Security Agency estimates that over 100 countries now have the ability to engage in or are developing the capability to engage in cyberwarfare. Many terrorist groups are apparently developing capability of committing cyber acts of terrorism.

The recent I Love You virus which I testified on earlier in the spring disabled the Centers for Disease Control to the extent that they said if they had had a major viral outbreak, they would have had a difficult time dealing with it. In a situation like that, where it's impossible to do inspections, the inspections aren't at all feasible, you'll have to do other things.

You'll have to have intelligence gathering activities that let you begin to assess what the threat might be and where the capabilities might lie. You need to think in a very proactive way about what your reaction might be to that threat if in fact it was realized, and what your recovery mechanisms would be. You also have to think about what you might do to investigate the cause of the action.

And some of the things that people are beginning to do in cyberterrorism might in fact be relevant to other aspects of weapons of mass destruction where inspections may not be the only way you want to have as a way of mitigating risk.

Mr. SHAYS. Very interesting. In your inspections, Mr. Brock, you gave a figure of $7,000, I think, to almost $100,000?

Mr. BROCK. Yes.

Mr. SHAYS. I can't visualize $100,000. I mean, I can visualize it, but I can't visualize why any inspection would cost that much.

Mr. BROCK. First of all, the company that did it had a very complete cost accounting system. And only two of the companies we visited had a cost accounting system that would allow them to more fully develop the costs that were associated with the inspection.

Mr. SHAYS. So you're suggesting that those that were less didn't maybe capture that full cost. So tell me about $100,000. What is done? Do people come into a plant and look at the plant? Why is it $100,000 to welcome them?

Mr. BROCK. First of all, some of the plants are more complex than other plants. The inspection itself is more complex and lasts longer. So there's a factor of time, how much time did the inspectors spend there. That's one of the things.

Mr. SHAYS. This is manhours. So in some cases, are we looking at an inspection that could take literally weeks?

Mr. BROCK. No. There's a limit on the inspection. In this case, 96 hours. Some companies captured the cost, if they had to shut down a production line, they would capture that cost. Some companies engaged outside counsel, because they were concerned about some of the legal ramifications. Some companies did more to cap-

ture the cost of the pre-inspection visits than other companies. They were just more complete.

I would suspect, I don't have direct evidence, I would suspect that if anything, the costs are underreported.

Mr. SHAYS. It's clear that if you have to shut down production, then you make the added mistake of hiring lawyers—[laughter.]

Mr. MAJAK. Mr. Chairman, since you invited comment from others, I might comment on that point.

Mr. SHAYS. The lawyers point? [Laughter.]

Mr. MAJAK. No, the Commerce Department's point. I'm not a lawyer and would not presume to make the lawyers comments.

But it was the Commerce Department that issued the regulations requiring the companies to report their costs, and we will be submitting to you later in the year under section 309 of the implementing act our data on the costs. And I take seriously Mr. Brock's recommendation that we look at the standardization of the accounting methods.

But I should explain that the reason we did not elaborate on those in the regulations is that we didn't want to force companies to create an accounting system that they didn't already have in place, and thereby incur even more costs. So we tried to leave it flexible for the companies. As a result, some have very precise cost accounting and others do not.

Certainly if it's the view of the committee and the view of GAO or others that we ought to standardize those requirements further, we'd be glad to work with the committee and others to do that. But I thought I should explain why we didn't spell it out more precisely.

Mr. SHAYS. Thank you. It's just that I had an advantage of going to Geneva and our committee look at what the Ambassador was doing and to talk to various people who were considering this issue. So I've had over a year to think about what you all are trying to do. And it boggles my mind.

And the more I know, the more I'm convinced that while the cold war is over, the world is a more dangerous place. And it's more dangerous because small, a small number of individuals can cause catastrophic harm to people around the world. And it makes me realize, ironically, why diplomacy is even more important. And why the ability to do extraordinarily fine intelligence work is more important.

As it relates to chemical, it's my understanding that if you inspect a chemical plant, you can't see a quick conversion to chemical weapon. There are chemical weapons that on the face can be used by terrorists. When the Colombians lost their version of their FBI, literally a nine story building was blown apart, 700 people injured, early part of the last decade, 70 people killed, because a terrorist had a chemical, an agricultural chemical, that they put in the back inside a bus, and blew up the bus and it blew the entire building up.

And that's a weapon. It's a chemical weapon, though, that frankly is just used as an explosive. And so an inspection would teach you nothing about that.

But let me just get a quick answer to this, and then I'd like to go to you, Dr. Koch. Can this committee make the assumption that

a biological facility can be converted in the next day where a chemical plant, if it's trying to weaponize a chemical, would have to have more time to go back and forth? Is anyone here capable of answering that?

Mr. MAJAK. Speaking from the commercial perspective, the activities that normally take place in commercial plants, I think you could make that conclusion, that certainly the first proposition is the case, that many of these plants are designed in such a way that they can change their production in a very short period of time, removing all traces of their earlier production. They do that obviously for legitimate commercial reasons, because they need to sanitize their facilities before they start producing something else. But they do have that capability.

Mr. SHAYS. I'd like to go to you, Dr. Koch, and if you would just explain to me, since we don't make biological weapons, what intelligence are we trying to protect?

Dr. KOCH. There are two basic categories of information, national security information, that we would want to protect under the measures foreseen in the protocol. The first for facility visits or investigations, there may within the same site be one laboratory engaged in activities directly relevant to the convention and another part of the facility engaged in something completely unrelated, but potentially quite sensitive.

This is an issue that we have faced, I think, with most arms control agreements with which I'm familiar with onsite inspections where parts of facilities that are engaged in sensitive activities that have nothing to do with that particular arms control agreement are protected.

Mr. SHAYS. Will you state for the record, we don't make biological weapons?

Dr. KOCH. No, we do not.

Mr. SHAYS. It's clear that a biological plant can be used to make a weaponized biological agent. What type of facilities that you can state for the record would our world partners be interested in inspecting, that is, of an intelligence nature?

Dr. KOCH. Well, the first category, as I said, would be just a universe of facilities where defense work is going on that has nothing to do with biological issues. The second——

Mr. SHAYS. Could you be more specific?

Dr. KOCH. Anything in the strategic area.

Mr. SHAYS. Well, they're not going to go to an airplane plant. What would they rightly say they have the ability to go to look at a biological agent? I'm looking at the confused faces and I'm confused too. It seems like a simple question.

Dr. KOCH. I would think one example may be, I'm not certain, for example, at our national laboratories. Some of our national laboratories are engaged in work related to biotechnology. They also are obviously engaged in much other national security work that has nothing to do with it.

Mr. SHAYS. Ambassador, do you want to add to that? You answered the question, Dr. Koch, I appreciate that. What would be another example?

Ambassador MAHLEY. Let me give you a couple of other examples. One of them is the fact that with outsourcing, you frequently

have contractors who are using high technology facilities for a number of different things. If for example one of the things that we're working on in the biological area is a very sensitive detection capability, you don't want to have the knowledge of how far you've gotten with that detection capability revealed to the international community.

Mr. SHAYS. That answers my question.

Dr. KOCH. That is the second category of areas in biodefense that might reveal vulnerabilities and gaps.

Mr. SHAYS. Sorry to interrupt you, Doctor, in your answer, but that helps some. So those two categories. You're saying Fort Dietrick would be an example? OK.

I'm inviting the counsels on minority and majority staff to ask some questions. I'm going to come back. Mr. Halloran will ask questions.

Mr. HALLORAN. Thank you.

Ambassador Mahley, if you would describe the kind of negotiating dynamics in Geneva at this point. There are, in the course of the 5-years various kinds of blocs of nations have emerged and various positions have been put on the table. Could you describe where the current posture of various international blocs might position themselves as you look toward the eventual conclusion, whether the United States is getting sort of isolated in its position at risk of looking like the bad guy here.

Ambassador MAHLEY. Well, thank you. I would prefer not to go into a great amount of speculation about where other countries are trying to go. But I think the answer I could give you to that is that the United States, first of all, is in a unique position in the world with respect to biology, both commercially and as a matter of defense. I think it's safe to say that the U.S. biodefense program, for example, probably constitutes more than half the expenditures in the world for biodefense.

So therefore, the number of things that we're doing and the number of places that we're trying to make progress, a lot of the results of which, as a matter of fact, would eventually be available to allies as part of defense sharing agreements, makes us pretty unique. Therefore, we have a range of things which we are concerned about in that area which some other countries, even countries from the western group, simply do not comprehend or do not contemplate. So that makes us, I think, more isolated than we might otherwise be with respect to the things that we need to try to defend.

Second, I think that there has been a dynamic in this negotiation, as I indicated in my statement, and as I indicated even more, I think, completely in my statement for the record, of competing objectives, and that is that there are countries who believe that national security gains from this protocol are relatively ephemeral and not particularly significant to them in their own context. In some cases, the United States disagrees with that, but nonetheless, this is what some of them, particularly the non-aligned, feel. And that instead, they see these negotiations as an opportunity to institutionalize access to technology and access to material and access to things that they believe are rightfully theirs as a result of the biotechnology explosion in the world, most of which is located in western countries.

In the process of that, some of them who have very legitimate objectives in terms of trying to simply get access to things they think will be helpful would of course by institutionalizing it open it up to where countries of concern would also have guaranteed access to the same kind of dual capability material. And again, I explained to the chairman earlier that the whole object from our standpoint is simply to complicate the life of a proliferator.

Well, one of the other ways you complicate the life of a proliferator is you complicate that by making it more difficult for them to get dual capable equipment. That's why we have export controls and that's why, as a matter of fact, we have the Australia Group, which does those sorts of things.

Those constitute, bluntly, national decisions, national decisions reinforced by the decisions of other like-minded states, which complicate the life of those proliferators. People view that, particularly among those who are potential recipients of those kinds of transfers, as being discriminatory. In some ways, they are discriminatory and hopefully they're discriminatory against those who have bad purposes.

At the same time, however, as I say, they don't like the idea that we make those on a national basis. That objective is one which we have fought from the beginning of the negotiations, that we will continue to fight and that we will not accept an adverse outcome on. And that insofar as we are prepared to be vocal about that, while others are prepared to hide behind our skirts, is something which leaves us more isolated, but it is not something in which we are alone. It is something in which we have a number of other like-minded countries who feel equally strongly about the same point, and that's just a question of what is the nature of the negotiating dynamic.

Finally, there are, I think, as this hearing has brought out, an enormous technical complication in terms of how you try to get things done in biology. And so therefore, there are still issues in which trying to find clear-cut ways to handle the concepts that are part of any kind of an arms control agreement, such as the universe of declared facilities in the biological field, to make that universe relevant, to make that universe limited, to make that universe clearly discrete. Those are issues which are still subject to some technical description, and in which we have fairly demanding standards.

But again, while I wouldn't say we were pushing the majority position, I wouldn't say that we were isolated. All of that is a negotiating dynamic exercised against a statement made in the 1996 review conference of the states parties to the Biological Weapons Convention, in which that review conference encouraged the ad hoc group to complete its work prior to the next review conference in 2001.

And there are a number of people who believe that is an absolute deadline, and that therefore, we absolutely have to try to finish this, and therefore go on, even if it's an imperfect product, into a conclusion that will occur before November 2001 when we will have the review conference. The United States does not agree with that. We certainly think that's an objective, we certainly think we're prepared to work very hard toward it.

But we are not prepared to accept an unacceptable protocol, simply to have something on paper that will be done by that time. That again is a position which is not universally shared. So that's the dynamic as best I can describe it. Thank you.

Mr. HALLORAN. Thank you.

Dr. Koch, in your description of the threat, I don't recall your mentioning potential leakage of former Soviet technology or technology from other established countries into states of concern. Could you elaborate on that in terms of the element of the threat that you see?

Dr. KOCH. That is certainly part of the threat, and we're engaged very actively with the most directly concerned states of the former Soviet Union, Russia, Uzbekistan and Kazakhstan, at the very least to prevent proliferation of such technology.

Mr. HALLORAN. Reading yesterday's Washington Post story, a question occurred to me, and I don't want to stray into classified information, but what is the more near term concern, the transfer of completed stocks, say, anthrax, for example, or of technology or expertise?

Dr. KOCH. I actually don't think we need to establish that priority. Because we're trying to work on both. Several cooperative projects funded by DOD, by State Department, Agriculture, increasingly HHS, with scientists in the former Soviet Union to engage them in peaceful work and give them alternate employment to any proliferation activities, or offensive, legal offensive activities at home.

And second, security efforts to safeguard the pathogens, plant, and animal and human pathogens that do exist in former biological weapons laboratories and that do have legitimate peaceful purposes. Again, as part of the dual use issue that we've been talking about for the overall convention, a facility in Russia can do legitimate work on smallpox. So they need the physical protection as well.

Mr. HALLORAN. Thank you. Finally, for Mr. Majak and Mr. Brock, in terms of CWC inspections you've seen, Mr. Majak, in your testimony, you said that while the inspection team has occasionally attempted to probe for information beyond the bounds of their mandate, most teams so far have had little difficulty keeping inspections on track. Would you elaborate on that in terms of what motivated straying from the assigned path and how it was made right?

Mr. MAJAK. Yes. The international inspectors have two purposes. One is to verify what the company has declared it is doing. The other is to as best they can determine that there are no schedule 1 materials on the site. Those are basically their two main goals.

And they probe rather vigorously. They're already well experienced. Although we've only done 10 inspections in the United States, these inspectors have done more than 200 inspections in other countries. So they've had a lot of practice, and they are aggressive in seeking the information they feel they need to satisfy those two purposes.

The Commerce Department, as the representative of the national authority, the representative of the U.S. Government on the site, we have helped the company prepare for those questions, we have

helped them identify what information they are obligated to provide under the treaty and what information they are not obligated to provide.

So there have been occurrences already in the first inspections where the inspectors have, in essence, tested the company by asking for things that are beyond the requirements of the treaty, and we have helped the company to fend off those kinds of inquiries. And the way they are fended off, we try to find alternative means of satisfying the inspectors. That is, what is the inspector trying to establish, is there another way we can do that.

Typically that would be, instead of looking at pipe or effluent X, we'll give you access to the records of what is going through that pipe. So we try to find alternative means of satisfying the inspector without revealing the company's confidential business information. But it does occur that the inspectors will ask for information which in our opinion goes beyond the scope of the treaty. And that's why the Commerce Department, a representative of the U.S. Government, is present, to help the company understand that they don't have to provide that information.

Mr. BROCK. Our experience in our actual visits supports that. The companies themselves are not particularly sophisticated in what these inspections entail. This is their first time to do it, and the inspectors are relatively sophisticated. The companies identified in a couple of examples where they were preparing to respond to an inspector's inquiry and representatives from either the Department of Commerce or the Department of Defense intervened and said that's not necessary to go to this level of detail, are there alternative ways of providing that information, because you're in danger of revealing proprietary information or processes. Which points out the importance of having absolute assurance that the teams, the Government teams, continue to be well trained and capable of providing support to the companies that do not have the experience to effectively deal with situations like that.

Mr. HALLORAN. Mr. Majak, are you involved in the administration preparations for the trial inspections that were put in the statute last year?

Mr. MAJAK. Yes, we are. We have been in contact with a number of private companies and industry associations to try to line up a facility that is both willing and suitable for a trial inspection. We were in fact a few weeks ago we thought relatively close to having such a facility identified. Unfortunately, in the meantime, the facility was sold to a new owner and the new owners were less willing to subject themselves to this than the previous owners.

But we will continue those efforts aggressively in order to fulfill the mandate of Congress and identify a private facility where we can conduct a trial investigation or a trial inspection.

Mr. HALLORAN. But it doesn't sound like you would have any results in time to do Ambassador Mahley any good in terms of the schedule he's on.

Mr. MAJAK. In terms of the negotiating schedule, you mean?

Mr. HALLORAN. Yes.

Mr. MAJAK. Probably not by the November negotiating round, no, we probably would not meet that. Although we'll make every effort to hold those trial inspections as soon as possible.

Mr. HALLORAN. And finally, if I might, Mr. Chairman, as you described it, Ambassador Mahley, it strikes me that given the modest goals of such a protocol, that is, to catch stupid violators and to catch poor, unsophisticated violators with an inspection regime, that there ought to be a mechanism to avoid spurious or pernicious accusations of violative conduct.

Where stands the draft protocol at this point on a threshold mechanism for an investigation?

Ambassador MAHLEY. I would just add to the idea of catching the stupid proliferator the idea that it's also hopefully going to deter and complicate things for the more sophisticated proliferators, as I said earlier.

Mr. SHAYS. You didn't make that case very well. [Laughter.]

Ambassador MAHLEY. But the other thing I would say is that where we stand on the threshold activity at the moment is that the draft, as it now stands, says that in order, you know, the state party to the protocol is one who would have to bring forth a request for a challenge activity. That challenge activity would then be reviewed by the executive council.

Now, what the executive council review amounts to is of course yet undecided. The U.S. position on that in this negotiation has been since 1998 that one would require that the executive council, which would be composed of some number of states parties, would have to by an affirmative vote of 51 percent of those present and voting, approve the request in order for the investigation to go forward.

That would allow us, we believe, an opportunity, for example, if there were a spurious request for an investigation, which is a more intrusive kind of onsite activity than any of the others contemplated, to be able to present rebuttal evidence and to be able to determine and make the case if it were spurious about why this was something that was not relevant to a biological weapons specification.

Mr. SHAYS. We're almost done here. Mr. Majak, I'd like you to tell me what the main points of contention or dispute affecting a working relationship between industry and the administration concerning BWC protocol. And I will just give an editorial comment and I'm sorry I can't ask the industry itself.

Mr. MAJAK. Well, first let me say we are in close touch with the industry, all the agencies at the table. We have an industry advisor group at the Commerce Department which includes a number of companies that could be affected by a protocol, so we're in close touch with them. Using as my guide the public position that PhRMA has specifically taken on the protocol, I note that PhRMA supports only at this point a challenge inspection procedure. It supports declarations that would not include any confidential business information. It does not support routine or random visits to facilities. I think those are the major elements.

It is willing to support purely voluntary educational visits to facilities. So I think those are the major points that the industry has publicly endorsed. While I would add one more, it favors a green light filter, so the necessity for multi-nation approval of any challenge inspection, I would defer to Ambassador Mahley to pinpoint where we are exactly in the negotiations on these points. We are

in negotiation on all of these points, and they change from time to time.

But my understanding is we are consistent with their position on challenge inspections, and green light filter for those. I think the negotiations have not yet determined the scope of the declarations. So it's difficult at this point to say whether there would be confidential business information included in the declarations or not. Our position does not include the use of routine or random visits.

And so I think we are responding in all of these areas to at least the industry's posture as it's been outlined by PhRMA. Ambassador Mahley may want to elaborate on that.

Mr. SHAYS. I'm struck by the fact that the Ambassador has to negotiate with more than one side.

Ambassador MAHLEY. Sir, it's a multi-lateral operation. That's not to be unusual.

Let me simply say to supplement what Roger said, and he's given you a pretty good summary at the moment, with respect to the information included in declarations, at the moment, the position that we have put on the floor is that confidential business information should not be, repeat, should not be included in any declaration. And that has fairly wide support in the ad hoc group. So I think that the idea of deliberately including confidential business information in the declaration is probably one that will not be pressed in the end.

Now, there are provisions in the protocol for a regime to make sure that if confidential business information is given to the organization, that it will be properly handled, such as in the Chemical Weapons Convention, there are provisions of confidentiality for highly sensitive information to be carefully controlled. At the same time, I think it is the position of the industry and certainly our position that the better thing to do with that is not let it out in the first place.

Mr. SHAYS. How many facilities, Mr. Majak, are we actually talking about, or Mr. Brock? How many facilities ultimately would need to be potentially inspected, or Dr. Koch, if you want to answer that, who's got the answer?

Mr. MAJAK. On the commercial side, the industrial side, we have 81 sites that are subject to inspection, because they are involved in either schedule 1, schedule 2 or schedule 3. And we would expect all of those to be inspected over the next couple of years, initially inspected and in some cases, followup inspections.

In addition to that, there are something over 600 declared facilities that declare so-called unscheduled organic chemicals. And in the long run, because it will take the OPCW, I think, some time to cover that territory, some or all of those could be inspected. But we expect the concentration of the inspections to be on the 81 facilities that are involved in schedule 1, 2 or 3.

Mr. SHAYS. Dr. Koch, from the Government side?

Dr. KOCH. For Defense Department, for the Chemical Weapons Convention, there are a total of 32 declared sites.

Mr. SHAYS. That's chemical?

Dr. KOCH. That's chemical. I believe Mr. Majak was speaking of chemical as well.

Mr. SHAYS. Were you speaking of chemical?

Mr. MAJAK. I was speaking of chemical. If I misunderstood your question—I was speaking of chemical facilities. We don't have such detailed information on the number of inspectable facilities in the biological area, because we don't know the scope of the protocol as well.

Mr. SHAYS. Ambassador, I must have been enjoying myself too much in Geneva, but I thought we had talked in the thousands. What am I mixing up here?

Mr. MAJAK. Again, speaking on the commercial side, there was a study done 10 years ago, at the outset of this process, which tried to estimate how many facilities would have to declare certain activities. Not all the declared facilities are inspectable, it depends on the volume of their production and other considerations.

The number of companies that actually did declare came in considerably below that, we think because there's been quite a bit of consolidation in the industry since that study was done. Some of them who were producing some of these controlled chemicals that they didn't really need commercially have taken steps to redesign their process to get out of that production. So we ended up with somewhat fewer declared companies that we had predicted 8 or 9 years ago.

Dr. KOCH. On the Defense side at this stage, it is quite difficult to estimate. So much will depend on the basic rules for declaring facilities. And it is one of many reasons that we place a high priority on a combination of the kind of activity going on and the level of effort to make a facility declarable. Because otherwise, for example, on the level of effort, an individual university researcher may be doing some relevant work. And in our view, and under the U.S. position, would not be declarable. But at this stage, it really is very difficult to estimate.

Ambassador MAHLEY. To clarify where we were a year ago in Geneva and where we are, we have not made a definition yet, or we have not made a determination yet of what is going to be the universe of declared facilities. And therefore, we can't make a prediction about how many of those there will be.

As of a year ago in Geneva, when you were there and we were talking about that, it was the case that a number of the declaration criteria which were then being put down on the floor and being advocated by various countries would have included thousands, literally, of U.S. installations. You'll recall earlier that I talked about the idea that there was a real difference between chemistry and biology here, in the sense that by getting schedule 1 and schedule 2, all of the firms that are involved in that, you've pretty much got the entire universe of those most relevant facilities to chemical weapons.

In biology, there is no such getting the entire universe. Because if you try to take all the places that have 50 liter or more fermenters, then you would indeed have thousands of facilities in the United States. In Iraq, they had a big biological weapons program that used principally 50 liter fermenters. So the issue is there.

So you're going to have to get some subset of that. What that subset will be and therefore the number of facilities that would end up being declared in the United States is unknown.

And I would add just one more point. In the currently envisioned regime, we would not have, even under the most aggressive proposals, routine inspections of all declared facilities. There would be some sort of a sampling of declared facilities. So the inspection liability from the United States under the worst possible case would be considerably lower than those that we have in the Chemical Weapons Convention.

Mr. SHAYS. A deterrent from robbing a bank is that if you're caught, you might end up going to jail. What's the deterrent if you make a chemical or biological agent?

Ambassador MAHLEY. First of all, in terms of the deterrents of making a chemical or biological agent, I would point out that we have domestic legislation which is fairly stiff in terms of doing those sorts of things. Internationally, if you as a country got caught either in the Chemical Weapons Convention, or as now proposed in the Biological Weapons Convention, making an illicit weapon, you could be subject to some trade restrictions or sanctions.

You could be refereed to the United Nations Security Council for whatever action the United Nations Security Council wishes to take against it, and you certainly would lose your privileges of voting or participation in the executive council in the organization.

Mr. SHAYS. You all have been wonderful witnesses. I have about 7 minutes to get to vote, but I always like to ask the question, what was the question you were prepared to answer that you wish I had asked? Any question or final comment? Is there a question I should have asked? Maybe you weren't even prepared, that needs to be on the record. Is there any? Any closing comments?

[No response.]

Mr. SHAYS. Well, then, we will adjourn this hearing. Thank you all for participating.

[Whereupon, at 12:15 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

**Industry-Government Cooperation and Lessons Learned on the Chemical Weapons Convention**

Written Statement
of the
American Chemistry Council

for the record of the

Oversight Hearing on the Biological Weapons Convention

of the

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

September 14, 2000

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**American Chemistry Council**

**Statement on the Chemical Weapons Convention Negotiations**

**September 14, 2000**

The American Chemistry Council[1] is pleased to submit this statement for the record to the House Government Reform Subcommittee on National Security, Veterans Affairs and International Relations on U.S. industry-government cooperation and lessons learned on the Chemical Weapons Convention (CWC) negotiations.

The Council supported the CWC treaty throughout its 20 year-long negotiation. The chemical industry believes that chemical weapons must be banned and we are committed to achieving the object and purpose of the CWC treaty. Our support for the treaty remains steadfast.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $435 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

Throughout the 20th Century, industry growth presented new concerns and challenges that the Council helped address, including chemical weapons proliferation. No commercial chemical company in the United States makes chemical weapons and the CWC treaty negotiations presented an opportunity to showcase industry's positive contribution to our overall quality of life. During the treaty's negotiation, ratification and implementation, we demonstrated how the products of chemistry themselves are used directly to improve the environment, protect health, or provide safety and how the business of chemistry is essential to our standard of living and the strength of the U.S. economy.

## CWC Treaty Negotiations

The Council has been involved in advocacy on the CWC treaty from the late 1970s and through the negotiations and ongoing implementation.

The chemical industry participated in the CWC negotiations out of contempt for chemical weapons as well as outrage over the misuse of legitimate products of chemistry as chemical weapons. That the chemical industry is a responsible and reliable partner in

[1] N.B. American Chemistry Council was formerly known as the Chemical Manufacturers Association.

stemming the spread of chemical weapons, is a concept embodied in the industry's Responsible Care® program.

Under the industry's voluntary Responsible Care® program, our member companies commit to continuously improve their health, safety and environmental performance. Responsible Care® also commits the industry to operate its companies in ethical ways that increasingly benefit society, the economy and the environment. Responsible Care® is now practiced in 42 countries around the globe.

**Lessons Learned from the CWC Treaty Negotiations**

The success of the industry's advocacy effort on the CWC treaty is due in large part to the unique relationship the industry has had with the United States Government (USG) throughout the treaty's negotiation, ratification and ongoing implementation.

The U.S. chemical industry and USG had one overriding objective - to outlaw chemical weapons. The Council also had a number of other practical advocacy objectives including to: 1) support a total ban on chemical weapons production; 2) minimize the administrative burden on industry, 3) maximize the protections for commercial information; and 4) reduce the possible intrusion into and disruption of company operations.

The USG appreciated and accounted for industry's advocacy objectives and we worked productively with each other toward the mutually shared goal of achieving a total ban on chemical weapons. Our relationship with the USG as well as the treaty secretariat functioned effectively due to open and regular dialogue and constructive cooperation. The result is a treaty that strikes a balance between the government's need for effective verification and protections for industry's confidential business information and commercial competitiveness. The essential point is that our relationship delivered the first global treaty outlawing a whole class of weapons and the first multilateral arms control initiative affecting the activities of a prosperous private sector enterprise, the U.S. chemical industry

The American chemical industry participated in the CWC treaty negotiations. First, we enlisted expert industry resources to examine the marketing, engineering, intellectual property and research aspects of CWC issues. These experts developed and defended consensus industry positions on priorities such as the protection of confidential business information and management of inspections. Our experts demonstrated the practical implications of CWC treaty implementation for the USG through the use of technical analyses, operational scenarios, and the conduct of mock inspections.

Second, we continually assessed the economic and commercial realities for the treaty's implementation in the U.S. Our technical expertise helped demonstrate to the Departments of State, Defense and Commerce how treaty covered chemicals could be used productively and positively in the modern manufacturing of plastics, pharmaceuticals and pesticides.

The industry also helped define confidential business information in the specific context of chemical manufacturing. We helped design declaration and inspection procedures that enable industry to satisfy its obligations while protecting its confidential business information.

The Council built a formidable national coalition of allied product organizations and associations, as well as an international coalition to represent the collective interests of the European, Canadian, Japanese and Australian chemical industries before the Organization for the Prohibition of Chemical Weapons (OPCW), which is responsible for worldwide administration of the CWC.

At the international level, we also advised negotiators on a confidentiality annex to the CWC treaty. The confidentiality annex provides general mechanisms for the ongoing protection of confidential information that might be required of commercial facilities in complying with the treaty. We also advised the OPCW on how proprietary information should be handled, and we developed verification measures that enable inspected facilities to protect proprietary information and manage inspector access.

Third, we explained the basis for industry support as well as the business of chemistry to CWC proponents and opponents alike. We countered the critics' claims of the CWC's catastrophic impact on industry and illustrated the CWC's reasonable and manageable approach to arms control.

Fourth, we pressure tested the U.S. system for CWC treaty implementation. Industry provided practical suggestions and proposed language on the U.S. implementing legislation and regulations. We conducted tabletop inspection exercises, participated in seven national level trial inspections and carried out a test run of the USG's electronic system for declaring or Data Entry Software for Industry (DESI).

The spirit of cooperation that characterized the industry-government relationship has helped to meet America's commitments under the CWC treaty. The net result of our advocacy is a treaty that imposes significant barriers to proliferators intent on manufacturing chemicals or diverting chemical shipments for proliferation purposes. The CWC demonstrates the effectiveness of a regulatory initiative carefully tailored to meet a stated policy objective.

The Council did not always agree with the USG. However, we always explored a range of options and alternatives. The Council recognized early on that a useful give and take between industry and government at both the national and international levels would involve regular trade-offs between the USG and other governments. We strongly believe that the CWC treaty is a measurably better product due to the Council's involvement and the broad-based support of other industry sectors and allies.

**Current Experience**

To date, the USG's management of CWC treaty implementation has been exceptional. The first phase of implementation that requires industry to submit initial declarations on CWC covered chemicals and activities is now complete. In March of this year, industry submitted 775 initial CWC declarations.

Inspection, the second phase of implementation, has just gotten underway. In May 2000, the USG hosted the first industry CWC inspection. While the industry's experience with CWC treaty inspections is limited, the Subcommittee's interest affords the perfect opportunity to reflect on our experience with the CWC treaty negotiations and look forward to realizing continuous improvements in national and international treaty implementation.

We welcome the Subcommittee's oversight of: 1) inspection costs under the CWC, pursuant to Section 309 (b) (5) of the Chemical Weapons Convention Implementation Act (CWCIA), passed May 23, 1997, and 15 CFR Section 717.4 of the Chemical Weapons Convention Regulations (CWCR), published December 16, 1999; and 2) protections for confidential business information under the treaty.

Regarding inspection costs, the Council originally estimated the cost of a routine on-site CWC inspection at $50,000. As of September 12, 2000, the USG had so far hosted 10 industry CWC inspections. The four Council member companies inspected thus far have not reported unforeseen or excessive costs, although the cost categories identified in Section 717.4 of the CWCR appear to vary from company to company. The legal and administrative costs naturally fluctuate from company to company with the costs of inspection varying according to the size and type of company operations and the type of inspection being conducted. However, we expect costs will decline on the whole as more experience is gained with the CWC verification regime.

The Council's entire advocacy effort on the CWC has been aimed at assuring industry compliance. A complete accounting of the direct and indirect costs associated with any inspection whether conducted by the Environmental Protection Agency (EPA) or Occupational Safety and Health Administration (OSHA) or under the CWC, is complicated. Industry expects future reports on inspection costs will improve Congress and industry's ability to manage CWC compliance costs.

With respect to confidential business information, industry is encouraged by the demonstrated effectiveness of protections for confidential business information. The Council is not aware of any failure or problems in protecting this information during industry CWC inspections. In the short time the CWC treaty has been in force, the Council is not aware that any proceedings to remedy the wrongful disclosure of confidential business information under Part D of the CWC's confidentiality annex have been invoked. No allegations have been made that commercial information has been wrongly disclosed

The four Council member companies inspected so far have generally expressed confidence in the USG's approach to implementation and in the USG host teams who have shown sound judgment and respect for private industry. In the Council's view, CWC implementation is going very well.

The Council continues to work closely with the USG to interpret fairly and consistently the terms of the treaty and text of the U.S. implementing legislation and regulations. To that end, we continue to:

- Have regular interaction with officials of the Departments of Commerce and State and Federal Bureau of Investigation to discuss ongoing implementation, lessons learned and areas for clarification and improvement;

- Draft industry guidance on declaration and inspection requirements under the treaty;

- Host industry inspection seminars with participation by officials of the Departments of State and Commerce, the Federal Bureau of Investigation and OPCW; and

- Continue to help resolve outstanding industry issues at the national and international levels.

Conclusions

The Council's experience illustrates that a partnership and an open dialogue between industry and government produces good results. The treaty is an unprecedented model of industry-government cooperation toward advancing peace and security and represents the potency of an industry and government partnership.

The story of significant societal and economic benefits from the business of chemistry underlies the CWC's reasoned approach to arms control. Industry's story will continue to be told through its ongoing involvement in the CWC's implementation and leadership in making a better, healthier and safer world through chemistry.

The Council and its member companies look forward to continuing to work in partnership with the USG in achieving the object and purpose of the CWC treaty.



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