

Statement of

MJ Lawrence Consulting

to the

**SEVENTH REVIEW CONFERENCE OF THE STATES PARTIES TO THE
BIOLOGICAL WEAPONS CONVENTION**

Presented by Mark L. Johnson, Munich, Germany

Geneva, December 6th, 2011

Mr. President, Mr. Secretary-General, and distinguished delegates. Thank you for this opportunity to make a statement at the Seventh Review Conference of the Biological Weapons Convention on behalf of MJ Lawrence Consulting. MJ Lawrence Consulting is based in Munich, Germany and independently facilitates communication between government and industry; specializing in the international availability of medical countermeasures against chemical, biological, and radiological agents.

At your last Review Conference, you agreed, in regard to Article VII that 35. *The Conference notes that State Parties' national preparedness contributes to international capabilities for response, investigation and mitigation of outbreaks of disease, including those due to alleged use of biological or toxin weapons.* Then at the Meeting of States Parties in 2010 you considered the *Provision of assistance and coordination with relevant organizations upon request by any State Party in the case of alleged use of biological or toxin weapons, including improving national capabilities for disease surveillance, detection and diagnosis and public health systems.* The outcome said (paragraph 19) that *...States Parties also recognised that capabilities to detect, quickly and effectively respond to, and recover from the alleged use of a biological or toxin weapon need to be in place before they are required.*

Mr. President,

Many States Parties lack medical countermeasures (MCMs) for responding to a bioterrorist attack. It is now widely recognized that terrorists could resort to using biological weapons. However, whilst the level of probability that such an attack will actually happen remains low, the MCMs required to respond to such an incident are expensive to develop and involve a lengthy process till they can be ready for use. If States Parties are to be prepared, they need to engage in a dialogue with industry on how to ensure that preparedness is improved and how this work can be financed.

The European Commission has shown particular foresight in the area of biopreparedness as demonstrated by its CBRN “green paper” initiative in 2007 and its corresponding CBRN action plan (15505/1/09 REV 1). Action H.35 of the plan requires that:

Each Member State should:

- *assess the required amounts and types of medical countermeasures in case of a incident involving high-risk CBRN materials;*
- *assess the possibility of sharing medical counter-measures across borders in case of an incident.*

However despite this encouraging Action Plan with Action H.35 to be implemented in 2011, the situation in regard to the 27 Member States of the EU in respect to MCMs and the funding to procure them is unclear. In contrast, the situation in the USA is better as the US agencies responsible for biopreparedness have indicated which vaccines, antivirals, immunoglobulin, etc. will be funded for development. This gives industry a greater guarantee that their products will have a market, and which will be put in reserve in the US Strategic National Stockpile. As a result, industrial stakeholders who develop and manufacture MCMs scale their resources and attention only to the US market, where their business models stand better chance of survival.

It is recommended that the States Parties should encourage the establishment of an open dialogue within States Parties between governments and industry so that bioterrorism preparedness can be improved. There is a real danger that in the absence of such dialogue, governments will rely solely on past experience gained from pandemic influenza vaccine and antibiotic preparedness. While there are some similarities to bioterrorist preparedness which can be relevant, there are also significant differences.

For example, flu vaccines and antibiotics are widely used to combat regularly and naturally occurring illness, even without threat of bioterrorist activity. Some analysts have estimated that by 2015 annual government spending worldwide on pandemic influenza preparedness will reach \$10 billion, with the global antibiotics market reaching \$40.3 billion. Accordingly, this market is lucrative and predictable, and large pharmaceutical/biotech corporations actively engage in wider investment. By comparison, there is little current demand for many MCMs against agents that could be used in a bioterrorist attack; consequently, a market currently only exists when governments perceive bioterrorist threat and communicate their associated requirements for preparedness measures to industry. Even for MCMs already developed, it is not feasible for businesses to create idle manufacturing capabilities and seek product licensing in the event that an emergency might happen.

Industry is thus waiting for States Parties around the world to clearly communicate which corresponding MCMs are needed as part of their preparedness plans to counter possible bioterrorist attacks. However, this type of communication is not happening. So the market, apart from within the US, is highly unpredictable and unprofitable, hence, industry cannot afford to devote its expertise and resources. This situation leaves many States Parties un-prepared for the worst that biological threats would inflict.

As John Abbott, chairman of the Interpol bioterrorism prevention steering group said in 2009: *"The threat of bioterrorism is for real and it is deadly as it has the potential to kill hundreds, thousands or even millions, but many nations still underestimate the need to prepare for such an attack."*

So, how can the international community balance this unpredictable demand with a clear need for solutions? First, it is time that States Parties around the world involve industry in a dialogue and communicate its requirements for MCMs. Equally, when such requirements are indicated, then industry will have to clearly specify to States Parties how, when, and if such requirements can be fulfilled. And if the threat estimates and the current capabilities do not match, then States Parties will then need to partner with industry to develop and manufacture those MCMs vital to a responsible biopreparedness plan. Supply cannot simply be turned on when governments are ready to receive. Yet dialogue alone will not be sufficient to create industry response to international demand. In many cases, governments will have to find ways to encourage businesses to develop and make their MCMs readily available.

Mr. President.

When you consider Article VII at this Review Conference, I recommend that you include in your Final Declaration language that recognizes the importance of States Parties engaging in dialogue with industry so as to ensure that the appropriate medical countermeasures (MCMs) are indeed available when they are required to counter an outbreak of disease, whether natural, accidental or deliberate.

Thank you, Mr. President.