

Prepared Statement of:

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**Project BioShield: Linking
Bioterrorism Threats and
Countermeasure Procurement to
Enhance Terrorism Preparedness**

The House Committee on Homeland
Security Subcommittee on Emergency
Preparedness, Science, and Technology

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Mr. Chairman, I thank you and the Committee Members for the opportunity to testify. The observations and recommendations I provide today are derived from both an entrepreneurial and scientific perspective. I am the Chairman, and CEO of Aethlon Medical, Inc., based in San Diego, California. Since 2001, my Company has focused on developing a therapeutic device able to deliver the immune response of clearing pathogens and related toxins from circulation. Our technology, known as the Hemopurifier™, converges the established principals of hemodialysis and affinity chromatography, with the recent discovery of affinity agents that are able to bind a broad spectrum of envelope viruses, including those that have been classified as bioterror threats.

Our scientific efforts have been supported and guided by a world-class team of infectious disease advisors, including the former head of the Russian Bioweapon Program, and the former Commander of Infectious Disease Research at USAMRIID, which today operates as our Nation's premier bioweapon research institute. We believe that the Hemopurifier will serve as an effective adjunctive therapy when treatment options exist, and most importantly, the Hemopurifier is available today as a first line of defense against drug and vaccine resistant bioweapons. This includes pathogens that have been genetically engineered for virulence and treatment resistance.

I should reference that the utilization of extracorporeal devices to filter or clear pathogens is not a novel concept. Hemofiltration was utilized in the Soviet Union in 1990 to save a bioweapon researcher from late stage Marburg infection. Leroy Richmond, a postal worker infected with Anthrax in the attacks of 2001, attributes the difference between his survival and the death of two co-workers as being a series of plasmapheresis procedures he received to combat circulating anthrax toxins. Today, Hemofiltration has evolved to be a common therapeutic intervention for the treatment of sepsis and septic shock, which is often the primary cause of death in viral infection.

Now that I have provided the Committee with background information, I wish to proceed with two comments related to current BioShield legislation.

1. Further Clarification in the Definition of Countermeasure – New BioShield legislation expands the definition of countermeasure to include the general term “therapeutics” but does not reference therapeutic devices specifically. In our pursuit of research grants at the NIH, we have found that the general term “therapeutic” for viral infection is traditionally considered by examiners to mean a drug or vaccine. In this regard, the definition of countermeasure should specify and include; “therapeutic devices that reduce viral load or modulate cytokine production”.
2. Presence of Non-Bioweapon Markets - Early versions of Project BioShield would have eliminated the consideration of a stockpile purchase if other significant markets existed for a countermeasure. Such language has since been revised to require that the presence of another commercial market must be factored into the HHS Secretary's decision to purchase a potential countermeasure. I believe that such open-ended language may deter organizations from pursuing the development of innovative therapies against biowarfare agents. This language is also counter intuitive as the best hope for treating such a wide range of threats is through the evolution of post-exposure immunotherapeutic countermeasures. Especially when considering the added challenge of combating pathogens that have been genetically modified. Therapies that are able to augment the immune function or modulate cytokine production are going to have large market opportunities beyond the treatment of bioweapons. If developed, these therapies would globally impact the treatment of infectious disease, including established pandemics such as HIV/AIDS, and new naturally evolving viral conditions. BioShield legislation should be embraced because of these possibilities. If the goal is to attract the development of treatment countermeasures, then references that imply the presence of a broader market as being potentially detrimental should be eliminated. In the case of Aethlon Medical, we are preparing to initiate human trials to treat HIV and Hepatitis-C. We do not have the luxury of betting the life of our Company on the hope that BioShield legislation will be inclusive of

our treatment technology. As the same time, our pursuit of other treatment markets should have no bearing as to whether our technology is stockpiled as a countermeasure against biowarfare agents. The stockpiling of our Hemopurifier should be based solely on its ability to save the lives of citizens exposed to biowarfare agents.

In closing, I thank you again for the opportunity to testify. Bioterrorism is clearly one of the most dangerous threats facing our nation, and I commended the committee members for devoting attention to this problem. I would now be pleased to address any questions you may have.

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