Testimony of

Mr. Alan Timmons

October 6, 2004

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Introduction

Chairman Hatch, Chairman Gregg, Senator Leahy, Senator Kennedy, and Members of the Committee:

My name is Alan Timmins and I am the President and Chief Operating Officer of AVI BioPharma, Inc. AVI is a biotechnology company based in Oregon which was founded in 1980 on the premise that genes could be the target for drug intervention. We have developed a proprietary third generation technology, distinct from that of any of our competitors, which we focus on unmet medical needs. We have conducted 11 human clinical trials with this technology in over 300 patients and shown our technology to be safe and efficacious in cardiovascular disease and modification of drug metabolism. We are currently conducting a controlled clinical study against West Nile Virus after finding that our technology is particularly germane to the field of infectious disease, specifically including agents that are considered bioterrorism threats.

Background and Applicability

The technology also lends itself to rapid response in a therapeutic setting. This was perhaps best illustrated by an incident in mid-February at the US Army Medical Research Institute of Infection Disease (USAMRIID) located within Fort Detrick, Maryland where a researcher experienced an accidental needle stick from a syringe containing Ebola Zaire virus. Ebola is a very lethal virus, historically fatal in more than 80% of infected individuals. Upon receiving a call from scientists at USAMRIID requesting our assistance, AVI found relevant genetic sequences, synthesized two drugs, assisted USAMRIID in securing an emergency IND from the FDA, and delivered those drugs to USAMRIID within 5 days of the original request. Fortunately, throughout twenty-one days of isolation, the researcher showed no Ebola symptoms and was released at the end of that time without requiring drug intervention. The same drugs delivered to USAMRIID have now been successfully put to use in ongoing research at USAMRIID, under a Collaborative Research and Development Agreement (CRADA) between AVI and USAMRIID.

AVI has ongoing programs with outside investigators in other infectious disease areas including efforts in Marburg, Dengue, Rift Valley Fever, Crimean Congo Fever, Ricin, E coli, Yellow Fever, influenza, Hantaan virus, and SARS. Clearly, all of these diseases or infectious agents are considered to be potential bioterror threats.

In addition to efforts in these areas, we believe that we are able to currently address more than 75% of the viruses on the CDC's list of bioterror agents. Further, the lessons learned from studies involving such an array of viruses to date offer the potential to create drugs for rapid response to engineered viruses designed as bioterrorism agents.

Impact of Proposed Legislation

The issue, however, is not the capabilities of my company, or any other company, small or large, to focus on infectious diseases in general, or on bioterrorism agents specifically. The issue is whether we will be able to bring any of this to market, for the defense of this country. This issue, therefore, depends in large measure on what you do here in terms of enacting BioShield II, and truly working to establish a biodefense industry in this country.

I have reviewed the proposals by Senators Lieberman and Hatch and offer the following comments to those proposals as they relate to smaller biotechnology companies like AVI BioPharma. As background, let me say that we are a small publicly traded biotech company that depends on the capital markets to fund our ongoing research and clinical programs. Critical to AVI, as to all small biotech companies, is our ongoing need to have favorable access to capital to fund product development, and to fund the clinical trials necessary to get those products to market.

Tax Incentives

Two of the tax incentives outlined by Senators Lieberman and Hatch will be seen as favorable by the capital markets. The R & D limited partnership structure, as proposed, would be attractive to investors because it would allow for current usage of deductions and credits by the partners, rather than only the possibility of future usage by the research organization. Also favorable to the capital market would be the capital gains incentive, because it helps to compensate investors for the perceived increase in risk that they bear with an investment in a biotechnology or biodefense company.

Patent Incentives

Similarly favorable to potential investors would be the proposed patent incentives. Though a non-cash benefit to the investor, the so called "wild card" patent extension, and related period of market exclusivity, would again be perceived as compensation for the increased risk shouldered by investors. Both the tax and patent incentives are critical to assisting in opening and maintaining the capital markets for biodefense companies.

Liability Protection

The most important incentives, however, both to the capital markets, and to the potential biodefense companies themselves are the liability protections proposed by Senators Lieberman and Hatch.

Most critical within those liability protections are the assurances of the government to the biopharma industry that the government will be a reliable, respectful, and responsible partner to biotechnology or pharmaceutical companies who join in the pursuit of bioterrorism agents. This should include guarantees that the patents and other intellectual property rights of such companies will not be "marched on" or threatened by the government, even under the stated intention of being "for the public good".

The possibilities of this occurring strikes fear in the hearts of all biotechnology or pharmaceutical executives in any company, large or small, in this country. Therefore, if strong, meaningful intellectual property protection is not extended to potential biodefense companies, then the risk to intellectual property will be perceived as too extreme, and the best of those companies will surely not participate in any biodefense effort.

Conclusion

In conclusion, to effectively address the ongoing threat of war carried out via bioterror means, you must do the following: first, effectively implement the original BioShield procurement provisions; second, enact tax incentives for investors who fund biodefense research; third, enact patent incentives including patent extensions and periods of market exclusivity; and fourth, commit to liability protection and specifically protect the intellectual property of companies participating in biodefense, and guarantee the effectiveness of the government as a partner in the biodefense industry. These actions will pay for themselves over the long run in the quality of response from the biotechnology and pharmaceutical industries. Further, these actions will represent tremendous strides in awakening and directing the entrepreneurial spirit of the biotechnology and pharmaceutical industries toward genuine progress in biodefense. I submit to you that if fostered and appropriately channeled, this entrepreneurial spirit will prove to be the most potent weapon of all in the war against bioterrorism.

I am happy to elaborate on any of these points. Thank you very much.