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Mr. Chairman and members of the subcommittee, thank you very much for inviting me to testify this morning. I appear before you this morning wearing two hats. I am the President and CEO of AVANT Immunotherapeutics, Inc., a biotechnology firm headquartered in Needham, Massachusetts. I am also a member of the Board of Directors of the Biotechnology Industry Organization (BIO). I appear representing BIO to address the subcommittee's concerns about how the Federal Government and the biotechnology industry should work together to meet the newly evident threat of bioterrorism. My comments are based, of course, on my experience as the CEO of a company that develops and produces vaccines that support that effort.

We sit this morning at ground zero of the new war against bioterrorism. Just yards from where we sit is where the anthrax-laden letter addressed to Senator Daschle was opened; just a mile away is the Brentwood facility where postal workers were lethally infected by the contents of that same letter. As awful as these events were, we all know that in some senses we were lucky in that a larger, coordinated, camouflaged anthrax attack could have been far deadlier.

As the federal government embarks on a campaign to fight bioterrorism and biological warfare, let me assure you that the biotechnology industry stands ready to contribute and work towards its success. The Biotechnology Industry Association (BIO) is made up of companies that develop and supply a wide variety of products essential to biodefense. Many are already working on defense-specific technologies under contract with the federal government, while others are at work on products that can be used for both conventional health care and biological defense. These technologies and products include vaccines to inoculate citizens against infectious agents, devices to detect biological or chemical attacks, enzymes to decontaminate buildings and people, tools to diagnose victims of these attacks, and therapies to treat them.

I think it is important to note that the entire biotechnology industry is absolutely opposed to the development of offensive biological weapons. This is BIO's longstanding policy, which is spelled out in the organization's Statement of Ethical Principles. The development and supply of biodefense products, however, is right in line with the central purpose of the industry, to save and improve the peoples' lives.

The President and Congress have made it clear that biodefense is a top national priority. Be assured that my firm and its fellow biotechnology companies stand poised to offer solutions to bioterrorism threats, both known and envisioned. Those that did not focus on the bioterror threat before last fall have certainly begun to direct their attention towards this crucial challenge. The question we all now face is how will the government enable our industry to contribute?

Let me speak briefly of how the biodefense effort looks from my vantage point. My company, AVANT, develops a variety of therapies that harness the body's immune system, including drugs to lower cholesterol levels, reduce the permanent damage inflicted by heart attacks and strokes, and prevent the rejection of transplanted organs and tissues. The area of AVANT's work most relevant to the national biodefense effort is our development of vaccines that fight both bacterial and viral diseases.

Our vaccine business to date has focused on the market for travelers' vaccines—protecting against cholera, typhoid, and dysentery—and on anti-viral vaccines to combat herpes, diarrhea in babies. However, we have worked with the Department of Defense, in particular the Army, in the biodefense effort even before September. One result of that work is that last October AVANT licensed its recombinant protective antigen for anthrax to Dynport Vaccine Company, a Defense Department contractor developing a second generation anthrax vaccine. This protective antigen is the crucial ingredient of an anthrax vaccine, the protein that prompts the body to develop immunity to the disease so that if the person is infected, it already has

protective antibodies in its arsenal.

Although we are proud of this contribution to the biodefense effort, we stand ready to play a much more significant role. Our most advanced technology offers the prospect of biodefense vaccines that are far more effective, safer, less expensive, and faster acting than current generations of vaccines. For example, the current inventory anthrax vaccine provided to U.S. troops is administered through multiple injections, which are often painful because of the reactive side effects of the vaccine. Once the series of injections is begun, immunity develops gradually over several months.

Compare this to the vaccine that we at AVANT, using our live attenuated vaccine vector technology, have successfully developed to fight cholera. This vaccine, called CholeraGarde, is administered in a single oral dose. It is safe and easily tolerated by the recipient. Immunity develops very quickly, in as little as 7 days. Manufacture of this vaccine is easy and inexpensive compared to current generation vaccines. While this particular vaccine fights cholera, our vector technology enables us to develop quickly an anthrax vaccine that is similarly effective, safe, and convenient. And we wouldn't have to stop there. Our technology enables us to adapt our vaccines to fight a wide range of bioterror agents.

As a biotech CEO, let me tell you the questions I would like answered as I consider whether and how my firm can contribute to this national effort.

1. What are the government's development and purchasing plans for biodefense products and systems? For vaccines, drugs, detections devices, and the entire array of biodefense materiel, what are the overarching goals and acquisition plans?

Before I, or any biotech executive, can make a decision about whether and how to provide biodefense products, we have to know what the government needs—what is the national plan. Formulating a single unified plan is no simple task, as there is no obvious authority to create such a plan. Before September 11, the biodefense program consisted principally of the Department of Defense effort to develop vaccines and treatments for forces in the field. That's why my company has worked with the Army on development of an improved anthrax vaccine since before September, for the purpose of inoculating U.S. troops. The Department of Health and Human Services played a key role in supporting research and development of related vaccines and drugs, but it had little active role in the procurement, stockpiling, and distribution of vaccines and other therapies for biodefense. My company's work with HHS has focused principally on basic research and clinical trials.

The new bioterrorism threat requires a capability to protect all Americans, military and civilian. Biodefense policymaking, previously split between two major agencies with divergent missions, must coalesce around a single national strategy. Acquisition authority and capability has been distributed widely among research labs and offices with varied program objectives. The

Federal Government must coordinate these authorities and assets to ensure a rational use of resources in support a unified biodefense plan. Once that single plan is formulated and made available, I can determine how my company can contribute to the national effort.

2. How will I access information about the national biodefense effort?

Once the Federal Government puts a national biodefense plan in place, it is vital that my fellow biotech executives and I have ready access to its contents in a usable form. There needs to be a clearinghouse for information that lets me know exactly which government agencies, offices, and labs are responsible for research, development, procurement, and policy relevant to my products.

Until such a resource is available, I will have to navigate a complex network of government entities, searching for the key contacts on vaccine development and biodefense procurement.

Until there is a biodefense liaison office to industry and a well-maintained website providing the latest details on national biodefense policy, my colleagues and I will spend significant time and money searching for where the real authority lies, wondering if we are talking to the right people.

Such a clearinghouse will make the biodefense effort more efficient for both the government and its aspiring biotech contractors.

3. Will the biotech community have input into the policymaking process?

There will be two key players in making the national biodefense plan succeed: the federal

government, which will determine goals, policy, and requirements and which will oversee the acquisition process; and industry, which will provide the goods and services the biodefense program requires. The national interest will best be served if the parties work together to formulate and implement the national program.

This may seem like an obvious and generally accepted recommendation, but I believe the particular case before us demands extra attention to the matter of government-industry collaboration. Although the federal government has done some business with the biotechnology industry, it is a mere fraction of the biodefense acquisition effort about to be launched. This leap in activity will make government and industry much closer partners, requiring far closer cooperation and deeper understanding of each other's goals and motivations.

From my perspective, I am most concerned that the government take into consideration the harsh economic realities of the modern biotech marketplace. Vaccine development, like development of any drug, is an extremely expensive and risky venture. Unlike the development of most drugs, vaccines have very limited sales potential, as the best vaccines eliminate their markets by eradicating the disease they target. Moreover, we have enormous liability issues as vaccines are generally administered to healthy individuals. All of these factors must be taken into account by the government as it considers the price and terms of contracts for the purchase of biodefense vaccines.

In summary Mr. Chairman, the biotechnology industry stands ready to join the Federal Government in meeting the nation's biodefense needs. We ask that for its part the government formulate a coordinated, coherent biodefense plan, that all aspects of the plan and its implementation are readily accessible to industry participants, and that both partners open a continuous dialogue about how to work together to meet the plan's vital goals. This plan should be accompanied by a clearinghouse of information on biodefense acquisition covering everything from policy to points of contact. If these steps are taken, we can look forward to a future where the best of our technical and management skills can protect all of us from some of the most terrifying threats of a new and dangerous era. Thank you very much.