TESTIMONY OF RICHARD HOLLIS,
CHAIRMAN AND CHIEF EXECUTIVE OFFICER,
HOLLIS-EDEN PHARMACEUTICALS,
BEFORE THE COMMITTEE ON ARMED FORCES,
SUBCOMMITTEE ON TACTICAL AIR AND LAND FORCES,
UNITED STATES HOUSE OF REPRESENTATIVES,
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Mr. Chairman, Ranking member Abercrombie, and other members of the Subcommittee, thank you for the opportunity to testify before you today. Mr. Chairman, before I begin, allow me to thank you personally for your longstanding efforts to help safeguard this nation against weapons of mass destruction (WMD).

My name is Richard Hollis. I'm Chairman and Chief Executive Officer of Hollis-Eden Pharmaceuticals (Hollis-Eden). Hollis-Eden is a San Diego-based biotechnology company, publicly traded on NASDAQ under the symbol "HEPH."

We appreciate this opportunity to testify before you today at the Small Business Innovation Hearing.

Our nation is now engaged in an asymmetrical war on terror. Our enemies don't fight in accordance with traditional rules of war or concepts of fairness. Our enemies don't differentiate between civilians and combatants; in fact, they specifically target civilians as soft targets. There are no clearly defined frontlines here; the battleground is as much Boston as Baghdad, Knoxville as Kabul.

A conventional war can be won by arming America's troops—the world's best-trained and most-dedicated fighting force—with advanced weapons systems. There isn't a fighting force in the world that can go toe-to-toe with our military. (And, large government contractors are often best suited to building such billion-dollar weapons systems.) However, this point isn't lost on our enemies. As a result, this isn't how today's wars are being fought. Defeating today's asymmetrical threats requires speed, ingenuity and innovation. Here I'm referring not just to our frontline units, but also to the industrial and scientific complex that supports our troops and provides for our national security.

The private sector is the engine of American innovation. And, within the private sector, it is small and medium-sized companies that are constantly and most rapidly pushing the envelope. Our company, Hollis-Eden, is a perfect example of that fact. In that vein, allow me to briefly reflect on our experiences as they exemplify both the challenges and opportunities.

For the last ten years, Hollis-Eden has been developing a proprietary class of compounds known as Immune Regulating Hormones (IRHs) for the treatment of infectious diseases and immune system disorders. Since 1997 the Armed Forces Radiobiology Research Institute (AFRRI), which is part of the Department of Defense, had been testing one of our drug candidates, at that time code named HE2100, in models of radiation injury and had reported positive results of these experiments in various medical journals and scientific

meetings. Shortly after the 9-11 attacks we were contacted by AFRRI and asked to develop HE2100, now called Neumune™, to protect victims of a nuclear or radiological attack or incident.

In a nuclear or radiological attack, the vast majority of victims would die from radiation sickness as opposed to the actual blast. For example, experts have concluded that a terrorist attack on New York City using a 12.5-kiloton device, which is relatively small by nuclear standards (it can fit in a briefcase), would kill roughly 250,000 people; 200,000 (or 80%) of whom would die from radiation sickness. Additionally, experts warn that in this scenario 700,000 additional people would suffer from various levels of radiation sickness. Radiation sickness kills and injures by damaging the body's bone marrow, which leads to depletion of white blood cells known as neutrophils, clotting elements called platelets and red blood cells which are critical for carrying oxygen to the tissues. This damage leaves the victim vulnerable to opportunistic infections, bleeding episodes and severe anemia, all of which can lead to rapid fatalities.

Neumune appears to work by boosting the body's ability to quickly recover from the bone marrow injury caused by radiation. Whereas today's treatment protocols would call for anyone exposed to even a moderate level of radiation to be hospitalized, thus completely swamping our healthcare systems, Neumune offers the opportunity to treat victims on an outpatient basis and potentially even allows patients to self-administer their therapy. In primate studies completed to date, whereas placebo treated animals experience prolonged periods of life-threatening loss of neutrophils, platelets and red blood cells, animals treated with Neumune show dramatic improvements in all of these critical cell types. No other currently available drug can provide this type of broad-spectrum protection. Neumune thus offers the potential to significantly improve survival rates in a mass casualty scenario. In fact, studies conducted by the military in rodents have shown that treatment with Neumune can lead to 100% survival in animals given a dose of radiation that leads to 100% mortality in placebo-treated animals. Importantly, Neumune is a compound that is practical and easy to administer on an outpatient basis at a fraction of the cost of hospitalizing those victims even if it were feasible to do so.

Prior to 9-11, Hollis-Eden was focused on a range of traditional market applications for this technology platform—infectious diseases such as HIV, malaria and tuberculosis, as well as a variety of autoimmune disorders such as multiple sclerosis and rheumatoid arthritis. While we continue to develop our technology for these other applications, in the wake of 9-11, we shifted the Company's primary focus to developing a nuclear antidote. Since our inception, the Company has invested nearly $100 million on the technology platform.

On two occasions (specifically the FY04 and FY05 House Reports on the Department of Defense Authorization Acts) this Congress has noted the progress in and importance of developing Neumune as a medical countermeasure against a nuclear attack. In both cases the House recommended increased spending to speed the development and deployment of Neumune. Despite this recognition, federal funding has been very slow in coming; to date, this compound has been developed almost exclusively with Hollis-Eden funds. Over the

last several years, we have invested tens of millions of dollars of the Company's money on this program.

We did so for several reasons.

First, we focused on developing Neumune because it was the right thing to do for our nation. We, like many others, believe that there is no greater threat to this nation than the nuclear threat. Let me briefly underscore this point with a few findings that have been reported in the press:

- Evidence discovered in Kabul, Afghanistan, including bomb design drawings and extensive downloaded materials on nuclear weapons, clearly demonstrates al Qaeda's interest in obtaining nuclear weapons.
- Osama Bin Laden himself has said that obtaining nuclear weapons is "a religious duty."
- Captured al Qaeda leader Abu Zubaydah has admitted that al Qaeda was working to build "dirty bombs," including those made from nuclear waste.
- There is evidence that al Qaeda has planned to attack nuclear facilities located here in the United States.
- Mohammed al Baradei, chief of the International Atomic Energy Agency, the United Nation's nuclear oversight agency, recently announced that the threat of a terrorist attack using nuclear weapons is "real and imminent." He called the threat a "race against time."

These findings must also be viewed in light of the current nuclear landscape:

- At the time of its break-up, the Soviet Union possessed enough weapons-grade nuclear material to make tens of thousands of nuclear warheads. Experts have testified that much of this stockpile is inappropriately protected or is unaccounted for.
- Outside the former Soviet Union, more than twenty tons of highly enriched uranium is spread across 130 civilian research facilities in 40 countries, many of which are secured by nothing more than a night watchman and a chain link fence.
- The International Atomic Energy Agency reports that there have already been 16 attempted thefts involving highly enriched uranium (HEU) and plutonium that we know about. One such incident involved the theft of roughly two kilograms of HEU from a research facility in the nation of Georgia. The whereabouts of this material remains unknown.
- Operational information about how to manufacture a basic nuclear device is available on the Internet and in library reading rooms around the world.
- Iran, which has a history of supporting terrorists, has restarted its nuclear program and is believed to be capable of producing weapons grade uranium.
- North Korea, which also has a history of supporting terrorists, continues to develop its nuclear program and is believed to have operational nuclear weapons capable of striking parts of the United States.

These risks must also be viewed in light of the strengths and weaknesses of our homeland security effort:

- Reports indicate that we inspect less than five percent of all cargo containers entering the United States.
- The General Accounting Office recently reported that the current system used to target high-risk cargo for inspection is fundamentally flawed.
- At last count we are aware of, only 100 of the 4,500 "C-TPAT" participants, whose cargo now is expedited and faces fewer, if any, inspections, have had their security procedures merely verified.

There is a very real risk that a terrorist could succeed in slipping a suitcase nuclear device into this nation and detonate it from a remote location. In such a scenario, the terrorist leaves no return address—making traditional notions of nuclear deterrence and defense outdated.

Based on these risks, we now conduct scores of drills designed to test our nation's ability to respond to a nuclear attack. In these drills, teams of medical professionals deploy to face what in reality would be casualties numbering in the tens or hundreds of thousands. These medical personnel are armed with little in the way of useful treatments to actually protect against the effects of radiation injury. For the vast majority of victims, we believe, absent deployment of a drug like Neumune, there is limited hope for the victims in a mass casualty scenario. And, this is to say nothing of how they will deal with the waves of worried well, who will inundate medical facilities and by their sheer number grind things to a gridlocked halt.

In these same exercises, we prepare to send National Guard Civil Support Units and first responders in to save lives. However, we cannot adequately protect these units against radiation. The protective gear these units now use cannot stop certain forms of radiation. And, in the case of a larger nuclear attack, we simply do not have enough protective gear for all our first responders. This leaves these vital individuals completely unprotected. If we deploy them into the hot areas where they can do the most good, we will lose them to radiation sickness.

The only way to save lives in the event of a nuclear attack is through an effective medical countermeasure. The only way to reduce the demand on medical facilities that will be stretched to the limit is by reducing the number of casualties, which requires a medical countermeasure. We can only effectively deploy National Guard and civilian first responders after a nuclear attack if we can truly protect them, and that will require a medical countermeasure. In other words, we can conduct drills all we want, but these drills will have limited utility until we can provide a practical and effective medical countermeasure.

We have also chosen to focus on Neumune because we believed it made smart business sense as a publicly traded company with fiduciary responsibility to its shareholders. The Food and Drug Administration's (FDA) drug approval rules provide a potentially expedited process for medical countermeasures to weapons of mass destruction

and one in which most of the development work is performed in animals rather than humans. By focusing on Neumune, we believe that we can develop this drug and get a product to market faster than if we focused on other medical applications.

While speed to market is important, in the end, there must be a market. Unlike most drugs, the private sector market for medical countermeasures to weapons of mass destruction is unclear at best—that is, until after an attack. This is a classic market failure. Absent a market, there is little financing for or investor interest in pursuing such drugs. As a result, the impetus is for companies to invest in more lucrative endeavors, such as finding the next Viagra.

The situation is akin to the government telling aircraft carrier manufacturers that it will no longer commit to buying carriers in advance, and that, instead, the manufacturers should simply build the ships, and if the government needs them down the road, the government will call. Obviously, if this were the case we would have no more carriers.

However, 18 months ago, in his State of the Union address, President Bush proposed Project BioShield. President Bush called for this program precisely to rectify the market failures I have described here. And, as proof the program could work, the market responded; our share price increased and it remained up until uncertainties about BioShield's fate caused the market to pull back from this sector.

BioShield has now passed both the House and Senate and it awaits House passage of what is essentially a conferenced version. We appreciate the hard work of this Congress in bringing BioShield to fruition and we look forward to its final passage and full implementation.

The purpose of BioShield is to provide the private sector with the necessary incentives to encourage investment in the development of medical countermeasures to weapons of mass destruction. Think of it as the "Field of Dreams": if you build it, we will buy it.

The promise of BioShield is not merely to have a dedicated funding source for medical countermeasures to weapons of mass destruction; rather, it is the ability to leverage private sector investment through early market signals. Under BioShield, the government can, and should, enter into scores of contracts with entities that may have the next cure for radiation, the Marburg virus, ricin, weaponized smallpox and other threats. The government bears virtually no risk here; the contracts only vest when an approved, effective and safe countermeasure is found. During the development process, the private sector can weigh the potential rewards and balance them against developmental risks. Investments will naturally track the most promising countermeasures, where risks are lower and the potential rewards are greater.

In our analysis, the combination of expedited FDA approval and the BioShield legislation made investing in a nuclear countermeasure a smart business decision.

That said, it has taken much longer to get BioShield passed than was originally anticipated, and the measure still hasn't been signed into law. We fully appreciate that the passage of legislation, and even the creation of a vital new federal program, are major endeavors that

require time, debate and thoughtful consideration. However, as this Subcommittee considers ways to more effectively harness the power of the private sector to defend this nation against terrorism and other emerging threats, you should be aware that the uncertainty surrounding BioShield's delay has played havoc on the ability of biotech companies to raise the capital needed to develop the medical countermeasures necessary to defend this country.

In order for the United States to develop the medical countermeasures required to safeguard the American people from WMD, two things need to happen. First, BioShield must be finally passed and signed into law. Second, the program must be implemented as it was rightly envisioned: not as a pool of money to be held uncommitted for procurement until drugs are successfully developed, but rather as a pool of money that can be committed to promising technologies early in the development process. The idea behind BioShield legislation was to have the government contracting process occur early enough in the development program that entrepreneurial companies could attract the necessary outside capital to allow these promising technologies to be developed. It was, in fact, this promise that allowed us to raise capital last year for Neumune. Unfortunately, the delays in enacting BioShield and the lack of clarity about what projects the government was truly prepared to support have caused our market capitalization to fall by 50% during a time in which we have otherwise significantly advanced the development of the program.

While we have continued to put our capital at risk for a program that still does not have a defined market, and are carrying forward in our efforts to scale up manufacturing despite not even knowing how many doses will be required, our Wall Street shareholders are clearly getting restless. We know of other biotechnology companies that have, in fact, shelved their biodefense programs despite having promising technologies because of these very concerns.

We understand that enactment of Project BioShield may finally be imminent, but there is still substantial uncertainty about how contracts will be awarded. We believe we have more than enough data today to justify a commitment for Neumune by the government. We understand, however, that there are agencies that are interpreting the legislation to not call for contracting of these products until an IND is filed to start human studies, a time when development is nearly complete. Whereas for traditional drug development an IND might be an appropriate point for contracting, in the area of countermeasures to weapons of mass destruction, all of the large efficacy studies are likely to be performed in animals before an IND is filed and human studies will just be performed to establish safety, after most of the risk and expense has been incurred.

We believe interpretation of this legislation that would delay contracting until an IND is filed thus runs counter to the intent of the legislation and will stifle investment in this area. It is hard enough to convince investors to invest capital in the early stages of the high-risk process of drug development even when they know there is a substantial market opportunity awaiting those that are successful. It will be much more difficult to do so if these investors will not have that assurance until the technical risk of product development has been greatly diminished and the bulk of the cost of development has already been incurred.

We would also encourage Congress to quickly take up further legislation that was contained in S666, which provided additional protection in the areas of indemnification and intellectual property protection as well as tax incentives to further encourage work in this area. While the intentions of BioShield are worthy, if the incentive structure is not sufficient, the output in terms of the number of new effective medical countermeasures will not be either.

Today's asymmetrical war cannot be won by firepower alone. The experts tell us that it is only a matter of time before a terrorist uses WMD against this nation. Simply put, you can't win an unconventional war using conventional weapons and tactics. You can't eliminate a deadly virus with an Abrams tank. A flak vest offers little protection against a nuclear or dirty bomb. However, medical countermeasures can literally take these weapons out of the hands of terrorists. The only question is: will we take the steps necessary to develop such countermeasures now, or only after it is too late?

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Just before the beginning of World War II, Albert Einstein and a number of other very distinguished scientists wrote to President Roosevelt to make him aware that the Nazis had begun efforts to develop a nuclear bomb. Sensing the danger, Roosevelt embarked upon the Manhattan Project, a joint effort of the public and private sectors, bringing together our brightest minds, to beat the Nazis to the bomb. The Manhattan Project culminated in the United States developing the first nuclear weapon. I raise this because it points out both the danger and the promise.

Since the end of World War II, mankind has lived with the fear of a nuclear bomb—a weapon so devastating that it is all but beyond our comprehension. In this era of terrorism and rogue nations the nuclear risk to our nation is, in my view, greater than ever before. The proliferation of these weapons and eventual use of a nuclear device against our great nation is the very real danger we face.

However, now, with Project BioShield, we can envision a new sort of Manhattan Project, one in which the strengths of the American government and our vibrant private sector are combined to win the "arms" race inherent in the war on terror. Today's arms race pits the terrorists, who want to use weapons of mass destruction, against our ability to find medical countermeasures to render such arms much less destructive. It is an interesting irony that one of the first threats that BioShield—a modern-era Manhattan Project—stands poised to defeat is the nuclear threat that the first Manhattan Project ushered in.

Confronted with the threat of nuclear weapons, President Roosevelt acted swiftly and boldly. We have no choice but to follow his example today in answering that same threat.

Mr. Chairman, Ranking Member Abercrombie, members of the Subcommittee, thank you for the opportunity to appear before you today.