

# The Threat and Promise of a new Biological World

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President Dye, Professor Levin, friends and colleagues,

I appreciate the opportunity to be with you today

It is a special pleasure for me to have the opportunity to return to my alma mater on this auspicious occasion and to participate in a conference designed to explore the future of science and society as we move into the 21st century.

*Oberlin provided to me the basic foundation in biology and chemistry that I needed, for that I have been ever grateful, but more than this, there was conveyed a broader context of understanding of the social sciences and an appreciation that the world was a far larger, complex and fascinating challenge than what I had previously travelled more than 200 miles from a Cleveland home. One inevitably learned other things about challenging authority and, perhaps ironically, that civil service, if being a part of government, was a respectable, high socially.*

It is generally agreed that the 21<sup>st</sup> century brings with it a <sup>dramatically</sup> new era in the biological sciences with advances in molecular biology and biotechnology that promise longer, healthier lives and the effective control, perhaps elimination of a host of acute and chronic diseases. *The prospects are bright but there is a dark side -- the possibility that infectious agents might be developed and produced as offensive weapons; that new or emergent infections, like HIV/AIDS, might overwhelm available preventive and therapeutic measures or that laboratory scientists, perhaps inadvertently, might create and release a new and lethal agent. These concerns are as relevant to Europe, to Africa, to Asia as they are to America. In today's world of rapid travel and large migrant populations, epidemic disease, wherever it occurs and of whatever origin, threatens the security of all nations: We are, today, ill-prepared to deal with these challenges, but this is changing more rapidly than is generally known and thus I will later describe*

Nothing in the realm of natural catastrophes or man-made disasters rivals the <sup>of previous</sup> <sup>potential and</sup> complexity of response that would follow a bioweapons attack against a civilian population. The consequence of such an attack would be an epidemic <sup>but</sup> and, in this <sup>scenario</sup> ~~country~~, we have had little experience in coping with epidemics. In fact, no city has had to deal with a truly serious epidemic accompanied by large numbers of cases and deaths since the 1918 influenza epidemic, more than two generations ago.

*just one year ago provided an unwelcome preview of a possible future*  
The anthrax release, although seemingly but a handful of cases, the repercussions were extraordinary. Those I was at the center were involved in 2003 given capsules a day and more than 100,000 of specimens were processed; the mail service was severely disrupted. Thousands of people stocked up on ciprofloxacin and many bought gas masks.

meetings with other agencies, the FBI and the WH and HHS.



Senators Hart and Rudman, chairs of the United States Commission on National Security in the Twenty-first Century, singled out bioweapons as ~~perhaps~~ <sup>perhaps</sup> the greatest threat that the U.S. might face in ~~the next~~ <sup>this</sup> century. Admiral Stansfield Turner pointed out that, besides nuclear weapons, the only other weapons with the capacity to take the nation past the "point of non-recovery" are the biological ones.

*Our now well-publicized of epidemic smallpox*

The Dark Winter scenario <sup>dramatizes</sup> the catastrophic potential of smallpox as a weapon. It is, of course, not the only possible organism that might be used. In 1993, the Office of Technology Assessment estimated that 100 grams of anthrax released upwind of a large American city - the model being Washington, DC - could cause between 130,000 and 3 million deaths, depending on the weather and other variables. This degree of carnage is in

the same range <sup>of</sup> as that forecast <sup>just detonation</sup> for a hydrogen bomb. ~~Although there is legitimate concern~~ <sup>could pose problems but</sup> about the possible use of chemical weapons, they are far less effective pound for pound and extremely difficult to deploy over large areas. ~~One hundred~~ <sup>One hundred</sup> grams of anthrax can produce as many casualties as a ton of a chemical nerve agent <sup>and we know what</sup> 10 grams can do when sent through the mails.

The insidious manner by which a biological attack would unfold is itself alarming. ~~The fact of an attack using an explosive or chemical weapon would be recognized immediately and resources summoned quickly to deal with the consequences and to begin to remediate the situation.~~ A biological agent would, in all probability, be released clandestinely as an aerosol spray, odorless and invisible, which would drift slowly throughout a building or across a city. Not until days to weeks later would people begin to fall ill; new cases would continue to occur over a period of one to several weeks. Some of those exposed, in all likelihood, would be hundreds of miles away when they developed symptoms -- in other cities, in other countries. Thus, the consequence of the attack would extend well beyond the immediate area of release.

*Why now are we concerned? Somewhat comfort in the fact such weapons have almost never been used. It is not that because it was believed they would not work.*

*never been used and assumes that they are at the outer limits of technology.*



As Gradon Carter <sup>has</sup> pointed out, the utility of bioweapons ~~had~~ been demonstrated by all possible means short of war. By the 1960s, the U.S. <sup>itself</sup> knew how to grow and process many microorganisms in a form usable for mass casualty ~~biological~~ weapons. Trials that modeled dispersion of simulant agents as aerosols were conducted in many cities/and scores of tests with live biological agents using animals as targets were performed at the Johnson Atoll from 1963 to 1969. There is now no doubt and there was then no doubt, of the capacity of these weapons to cause widespread casualties. ~~A World Health Organization (WHO) analysis, now 30 years old, supported the belief that biological weapons are strategic, population-destroying weapons. Since then, the technology needed to create and disperse these weapons has advanced significantly.~~

The year 1972 was a significant one in the history of bioweapons. That year, the Biological Weapons Convention was agreed upon, calling for all signatory countries to cease research on biological weapons and to destroy existing stocks. <sup>Virtually all countries, including our own, were signatories</sup> The Soviet Union and Iraq were both parties to the Convention. <sup>(responded in a Cold War context and</sup> The Soviet Union, however, began

~~immediately to greatly expand and modernize its existing biological weapons program, and to develop genetically engineered pathogens and other organisms that could serve as strategic weapons.~~ A new organization was created called Biopreparat. Ostensibly a civilian operation, it recruited some of the most capable of Russian biologists. At its peak, <sup>(the bioweapons program 60,000)</sup> it employed over ~~60,000~~ persons. ~~There was also a military program of at least 15,000 people and an agricultural program making crop pathogens that employed 10,000 people.~~ The overall complement of staff was equivalent in size to that of its nuclear program. Biopreparat's agenda included the manipulation of viruses and micro-organisms to render them capable of surviving delivery on missile warheads; the development of particularly virulent strains of organisms that are resistant to vaccines and antibiotics; the creation of peptides that could alter moods and heart biorhythms; and the manufacture of tons of anthrax, as well as smallpox virus and antibiotic-resistant strains of plague.

~~Although~~ the Soviet program was <sup>Hareoc,</sup> ~~of~~ prodigious size and sophistication, the infrastructure that is actually necessary to make a biological weapon is, in fact, comparatively simple and inexpensive, especially compared to that required to make a nuclear weapon. To make one kilogram of plutonium requires 100 tons of uranium ore; a substantial quantity of specialized equipment; and an enormous facility readily visible from the air. ~~It~~

*and this has been discovered and confirmed by <sup>my</sup> member of Dept. Two  
Significant parts of it are still intact.*



A biological weapon can be produced with the same equipment one uses to produce an ordinary vaccine; it can be readily housed in a building the size of a two-car garage; ~~nothing on the exterior would identify its use.~~ Moreover, the room and the equipment ~~could~~ be sufficiently cleansed within 24 hours so that no one, on inspection, would be able to determine whether it had been used to make vaccines or biological weapons.

The intelligence agencies have estimated that at least a dozen states possess or are actively seeking an offensive biological weapons capacity. ~~Most of these states are those named by the State Department as sponsors of terrorism.~~ Expertise for operating these facilities is readily available from now poorly funded laboratories of the Russian biological weapons complex. ~~For these countries,~~ biological weapons have a special appeal. They are inexpensive, they occupy little volume, they are readily transportable from place to place and they are capable of being disseminated covertly so that attribution may be impossible.

~~It is also important to appreciate that the technologies needed to build biological weapons are available in the open literature and on the Internet. This is not knowledge that is limited to a few hundred scientists isolated in a laboratory in the western desert. There are many scientists who have this knowledge and are capable of putting together a biological weapon~~

A heightened  
 A ~~key~~ reason for being concerned about biological weapons is the remarkable progress now being made in biotechnology and genomics research. Unfortunately, as

~~Indeed, it is generally acknowledged that the life sciences will be the most important technology of this century.~~

~~But, as the understanding of molecular biology increases and as we develop the ability to manipulate cellular processes, we are also creating the tools and knowledge for building more powerful and more diverse weapons. When we discover why a particular virus or bacteria is especially virulent or why it has become resistant to antibiotics, we create an opening for building a new drug or a new vaccine. At the same time, we facilitate the creation of tools needed to build more virulent weapons.~~

- 1995 marked a decisive turning point in U.S. concerns about bioterrorism.
- o the speed of developments in Russia were becoming clear
  - o Aum Shu-ryu
  - o Iraq



It is difficult to imagine how the public might respond in today's world to a fast-moving lethal epidemic. In recent decades, there have been few such epidemics in industrialized cities. One of the more recent occurred in India in 1994. Plague broke out in the diamond-polishing district of Surat. It was reported by the media as a deadly, mysterious fever, possibly plague. Within hours, panic reigned. People began streaming from the city. Many in the medical community were among the first to leave. Eventually half a million fled, leaving the city a ghost town. It is estimated that India lost some two billion dollars in lost trade, embargoes, and production as a consequence of this outbreak. How many actually died of plague is still not clear but the total was not more than 50.

Epidemics have the potential to spread internationally as we have observed with the HIV/AIDS epidemic. The disease is contagious but it is not easily transmitted from one person to another. Nevertheless, it spread across the globe and is changing the population demographics in some African countries to a degree comparable to that caused by the Black Death of the 1300s, which killed a third of the European population.

*Addressing the Threat*

*Clinton needs special*

*Departments make* Beginning in 1995, *Efforts run the last 5 years* when the first Presidential Decision Directive ~~was~~ *requiring that* issued, preparations to respond to terrorism focussed almost exclusively on training and equipping "first response" teams to counter the effects of a nuclear or conventional

explosive device or a chemical attack. Training programs in 120 cities were targeted to include police, fire and emergency rescue personnel in a "lights and sirens" type of response and special full-time units of the National Guard were constituted ~~whose function is not clear but certainly have little to do with bioterrorism.~~

*biological weapons were the main of great concern and that the*

Not for several years was there a beginning comprehension that the ~~consequences of use of a biological weapon would be an epidemic~~ and that those first detecting its presence and those primarily responsible for controlling the disease would be public health

*Until 1999,*

personnel and physicians. Accordingly, ~~in most cities, public health, medical and hospital personnel were not included either in planning or training.~~ *At that time limited* Finally, in FY99, significant funds ~~began to be~~ *were first* made available to the Department of Health and Human Services,

*It's* primarily the Centers for Disease Control (CDC), ~~whose~~ traditional responsibility, with state and local health departments, has been the surveillance and control of infectious diseases. ~~Some two~~ *Just three* years ago an Office dealing with Bioterrorism was established at CDC; modest funds began to be made available to the states for development of programs,



12 months ago, things changed

dramatically changed priorities, in January this year

~~Responding~~ to the events of 9/11 and the subsequent anthrax release, the Congress made available funds for major new initiatives to be undertaken by the Department of Health and Human Services – in all, some \$3 billion, ten times the amount available only one year before. Secretary Thompson created a new Office to oversee the new initiative. ~~It was~~ <sup>We did</sup> not call ~~ed~~ <sup>it</sup> the Office of Counter Terrorism, nor an Office of Biological Weapons Defense. Rather, it was called the Office of Public Health Preparedness. I was charged with the responsibility for direction of that Office <sup>ad for \$3 billion.</sup>

The name of the Office was selected deliberately to recognize the need for a broad-based <sup>public health and medical</sup> program, ready and capable to detect, define and respond to biological threats from whatever source, whether deliberately released by man or arising naturally such as did HIV/AIDS <sup>West Nile encephalitis or</sup> or perhaps inadvertently created by a scientist in the course of genetic manipulation of organisms.

The recent concern and debate about biological weapons has resulted in a constructive reexamination of the challenges now being posed <sup>to</sup> by the biological sciences ~~and~~ by the microbial world and discussions as to what policies we might need to adapt to meet these challenges. Let me explain briefly.

It is generally conceded that during the last half century, the physical sciences predominated on the research stage – the era of the atom, of nuclear fission, of rocketry and space travel. However, Dr. Alan Bromley, a prominent physicist with whom I served <sup>10 years ago</sup> as Science Advisor to President Bush, perceived that during the 21<sup>st</sup> century, the biological sciences would assume the <sup>prominent</sup> ~~predominant~~ role and this, indeed, is what is happening as we explore, down to sub-molecular level, our own genetic constitution and behavior, the biochemistry of response and the world of living matter. Sophisticated

techniques for genetic manipulation of organisms are now widely applied in laboratories around the world extending from sophisticated research institutes across a spectrum that embraces even high school science labs. Our horizons are broadening exponentially, ~~and~~

~~new~~ therapeutic agents are being discovered daily. *That we cannot ignore is that*

~~But there is a~~ dark side. Organisms with lethal properties can now be manipulated and produced ~~readily~~ *readily* at many different sites and by many different persons -- inexpensively. The quantities needed to create extraordinary mischief are not large; and they are all but impossible to detect either in process or in transit.

What is not immediately known is readily recovered from the Internet -- indeed, detailed instructions as to how to weaponize various organisms was, until very recently, readily recoverable from several websites. There is today real concern as to how best to deal

with these issues without strangling science. *These challenges are new and different from those we have heretofore known.*

At the same time, we are encountering, with ever greater frequency, new and emergent organisms, some posing very serious problems indeed -- HIV/AIDS, mad cow disease, West Nile encephalitis and many others. Pandemic influenza remains an ever worrisome threat. Little known is the fact that a new strain of influenza, called H5N1, appeared in Hong Kong only three years back. It infected only 18 persons but killed 6.

*Sporadic* ~~Occasional~~ isolations continue to be made but, so far, it has not yet shown a tendency to spread widely. *We don't know why* Chickens, in large numbers have been afflicted and each time of ~~its~~ *of the next strain* appearance, tens of millions have been killed. *in order to diminish the likelihood of its spread. but we not forget, however, so good but* all organisms are

continually mutating and changing, with those that infect best usually getting the upper *Population in developing countries are malnourished and densely crowded with thousands in tropical* hand. ~~Exploding urban populations, living in poverty in third world~~ countries, provide

fertile ground for new or mutant organisms to establish themselves. Enormous numbers



of travelers now probe some of the most distant areas and move across the world in unprecedented numbers. Epidemic disease anywhere is a threat to <sup>all continents</sup> ~~ourselves and others~~ as ~~never~~ <sup>has</sup> never before <sup>occurred. For us, the protocols</sup> ~~existed~~ <sup>discussed</sup>. The isolation provided once by two oceans has essentially vanished. (Madonia near Maryland)

~~The~~ <sup>Our</sup> Department's program of Public Health Preparedness has thus been designed and is being developed as a broad-based program to detect, at the earliest possible time, outbreaks of disease of whatever origin, to be able to diagnose them quickly and to respond promptly with medical care, patient isolation, and ~~drugs~~ or vaccines as needed.

More than half of all resources <sup>resources - about \$1.5 billion</sup> are focused on the development of state and local ~~responses~~. The laboratory capacities of a network of some 150 labs are being expanded; communications networks are being installed to permit the prompt exchange of

information between hospital emergency rooms, public health officials, infectious disease specialists and police and emergency medical groups. <sup>All states and larger H.D. are in 24/7</sup> Twelve emergency stocks of

drugs and medical equipment are now in place that can reach any site in the country within 12 hours with enough antibiotics to treat as many as 20 million persons for 60

days. <sup>On Sept 20, we had just 90,000 doses of ipox vaccine</sup> Special training programs are now being provided and more are planned. Over

200 million doses of smallpox vaccine is now available should it be needed and more will be delivered by the end of the year. A new anthrax vaccine is in an advanced

development stage and hopefully will see its way into field use within 2 years. And, of course, we are working closely with health authorities in other parts of the world to

heighten our preparedness globally as epidemic disease anywhere can threaten security across the globe.



One of our highest priorities

High priority is now being given to mounting a robust research and development program that spans the spectrum from basic research into pathogen life cycles and human immune responses to advanced development programs to permit the more rapid diagnosis of diseases of all types and techniques for the rapid production of antimicrobial agents, vaccines and chemical substances that could enhance the response of the immune system.

\$1.5 billion made available from multi-institutional centers of excellence to be awarded

In brief, the programs are envisaged to be long-term. The problems ~~discussed~~ <sup>discussed</sup> are not going to disappear. It is a new world we face and it is the biological

agents that represent a special and very serious challenge.

7 smallpox

I paraphrase Dr. Josh Lederberg, Nobel Laureate and former President of Rockefeller University. As he said, "Man's only <sup>competitor</sup> ~~challenge~~ for dominion of the planet are the viruses - and the ultimate outcome is not foreordained."

We are <sup>now</sup> ~~firmly~~ committed and working hard to strengthen the odds of human pre-eminence!

Air Force 1