Highlights of the 2005 Topical Meeting: Innovations in Mitigating BioThreats

Fraunhofer USA, Inc. and its Center for Molecular Biotechnology hosted the Topical Meeting ***Innovations in Mitigating BioThreats*** on July 18, 2005 at the Hotel DuPont in Wilmington, Delaware.

Fraunhofer USA

The first Fraunhofer Topical Meeting "*Innovations in Mitigating Biothreats*", was designed **to raise public awareness and promote the implementation of technological advances that will facilitate developing biomedical countermeasures against infectious diseases**. This unique gathering of experts from academia, industry and government, featured sessions on "**Biodefense", "Advances in Disease Prevention, Public Health**", and "**Advances in Disease Prevention, Agriculture**" "An objective of this meeting is to take steps towards understanding and consolidating efforts of all sectors to combat sudden outbreaks of disease, natural or man-made", said Dr. William Hartman, Vice President of Fraunhofer USA, Inc.

Throughout history, diseases caused by **bacterial and viral infections** have had dramatic impact on human health. The socio-economic devastation caused by these outbreaks, such as plague and Spanish influenza, are still being felt today. In spite of all the cutting-edge developments in biotechnology and biomedical sciences, man is still not fully prepared to neutralize the impact of disease outbreaks. The recent SARS outbreak and its consequences revealed man's vulnerability and reinforced the need for the development of new technologies and processes that will prepare us for dealing with the sudden emergence of such outbreaks. The current spread of **bird flu** that can infect humans, and could potentially cause the next pandemic, indicates the urgency of the problem and dictates the need for concerted efforts from academia, industry and the government to develop countermeasures. The terrorist attacks of 9/11 and the **anthrax** letters further complicated the problem. Intentional release of infectious agents, a form of bioterrorism, causes human casualties with devastating social and economic consequences. Hundreds of institutions, worldwide, have increased their efforts to deal with these challenges. A concerted effort by those involved, however, would facilitate effective and efficient implementation of new relevant cutting-edge technologies, put processes and policies in place, and prepare authorities to respond more efficiently to sudden outbreaks of infectious diseases or man-made spread of biological agents. The aim of this first Fraunhofer USA Topical meeting was to initiate such a concerted effort and to make representatives of the different agencies aware of not only the progress made but also the challenges each sector faces in addressing the very same common problem. Distinguished speakers from several countries, representing key agencies, addressed the audience outlining their strategies to control and prevent disease.

The session on **Biodefense**, chaired by Dr. Vidadi Yusibov, Executive Director, Fraunhofer Center for Molecular Biotechnology (CMB), focused on progress in developing biomedical countermeasures against biowarfare agents. The speakers outlined the need for safer, faster, and more economic technologies for producing large volumes of readily available vaccines, therapeutic antibodies and antimicrobials.

Pictured from top to bottom, left to right: Sen. Tom Carper with Hans-Jörg Bullinger and Dennis Tsichritzis, Darrell Galloway, Ken Millburne, Charles Penn, U.S. Congressman Mike Castle, Nancy Cox, Ed Levine.







Ed Levine, Senior Professional Staff Member of the Senate Foreign Relations Committee, represented Senator Biden. He stated that Senator Biden believes that it is imperative that we have better disease surveillance world-wide, among both humans and animals. Senator Biden's Global Pathogen Surveillance Act will increase U.S. assistance to developing countries to enable them to monitor and report on disease outbreaks, with particular emphasis on outbreaks that could be the result of bioterrorist activity. In addition, we need **faster and less expensive production of safe and reliable vaccines**.

Senator Biden is very proud to be a supporter of Fraunhofer's work for the United States Navy on a new anthrax vaccine.

U.S. Navy Capt. Darrell Galloway, Captain USNR Chief, Medical Programs, Joint Science and Technology Office of Chem-Bio Defense, **Defense Threat Reduction Agency**, spoke about current DoD research, and the changing paradigm. He stressed the importance of biodefense research, nothing that his budget has been increased by 80% for 2006. Captain Galloway also spoke about different strategies that DoD is pursuing to deal with different biothreat agents, such as smallpox and botulinum toxin, and alternative ways to deliver vaccines.

Ken Millburne, Biodefense Program Manager of the **National Institute of Allergy and Infectious Diseases** (NIAID) discussed the current programs in Biodefense Research at NIAID.

Dr. Vidadi Yusibov, Executive Director, CMB, presented aspects of **plant-based technologies** developed at CMB, emphasizing the potential of these technologies to address some of the shortcomings of current vaccine development strategies.

Dr. Charles Penn, Head of Research and Development, Health Protection Agency, **Center for Emergency Preparedness and Response**, Porton Down, UK, spoke about new vaccines for bio-threat agents as well as opportunities, challenges and risks. Dr. Penn also emphasized the need for further studies on innate immunity.

Speakers also stressed the need for new, more efficient models for transitioning discovery research into product development.

The session "**Advances in Disease Prevention, Public Health**", chaired by Dr. Geoffrey Schild, Chief Scientific Officer, **Integrated Biopharma, Inc.**, focused on infectious diseases that are a serious public health concern. A major part of this session was dedicated to influenza, an emerging pandemic threat. World-renowned authorities on influenza spoke to the audience. Dr. Nancy Cox, Chief, Influenza Branch, National Center for Infectious Diseases, **Center for Disease Control**, spoke about "Influenza: Tracking a Moving Target". Dr. Cox described the tremendous efforts that are being made not only in vaccine development, but also in tracking the movement of the virus. In coordination with the **WHO**, 114 laboratories in 83 countries, are involved in collecting epidemiological information to develop measures to counteract the next pandemic.

Dr. James Robertson, Principal Scientist in Virology, **National Institute for Biological Standards and Controls**, UK, spoke about "Preparing for the Inevitable-Pandemic Influenza".

Dr. Douglas Holtzman, **Bill and Melinda Gates Foundation**, spoke on "Public-Private Partnerships for the Advancement of International Health". Dr. Holtzman's talk highlighted the importance of public and private partnerships in resolving some of the challenges the world faces. The mission of Global Health Program of the Gates Foundation is "to ensure that people in the developing world have the same chance for good health as people in the developed world". The Foundations aim is to "save millions of lives through the development and distribution of health tools and strategies – some new, some already in use". CMB is a recipient of funding from the Gates Foundation to develop a plant–based vaccine against sleeping sickness, a devastating disease of cattle and humans in Africa.

Although human health and the pathogens related to it are always the focal point of biomedi-

Pictured from top to bottom: William Hartman, John DiEleuterio, Doug Holtzman, Geoffrey Schild, Phillip Berger, Loren Babiuk, Robin Morgan. Photo in center: Martina Schraudner, Anke Hellwig, Loren Babiuk and Geoffrey Schild.

cal research, biothreats to agriculture are no less damaging to the health and economy of any country. The session, "**Advances in Disease Prevention, Agriculture**", was chaired by Dr. Lorne Babiuk, Director, **Vaccine and Infectious Disease Organization** (VIDO), Canada. Dr. Phillip Berger, National Science Program Leader, **USDA**-Center for Plant Health Science and Technology, Plant and Quarantine Service (APHIS_PPQ), spoke about the various infectious diseases of plants, the spread of insect vectors that carry disease, and the efforts being made by USDA in conjunction with other agencies worldwide, for the diagnosis, prevention, and control of plant and animal diseases.

Dr. Babiuk spoke on "Reducing the Economic Threats of Infectious Diseases to the North

American Economy". He described the devastating impact that outbreaks such as foot and mouth disease, Avian Influenza, and mad cow disease, could have on the local and global economy. Dr. Babiuk also spoke of some advances made at VIDO in the development of vaccines to protect animals.

Dr. Robin Morgan, Dean of the **College of Agriculture and Natural Resources**, University of Delaware, explained "The Role of a Land-Grant University in the Practice of Agriculture". Dr. Morgan stated the purpose of a land-grant university, is to "apply knowledge and improve the quality of life for the citizens and communities of the state". The Dean shared information on education and research being conducted at the University that address concerns related to the chicken and soybean industry, two major sources of revenue for the State of Delaware.

The importance of attracting biotechnology businesses to Delaware and developing successful partnering relationships was addressed by: Michael Bowman, Chairman and President of the Delaware Technology Park, in which CMB is located; Dr. Orn Adalsteinsson, President and CEO INB-Biotechnologies, Inc., with whom Fraunhofer CMB has joint projects; and Judy McKinney-Cherry, Director of the Delaware Economic Development Office, a provider of seed funding to CMB.

U.S. Senator Thomas Carper and U.S. Congressman Mike Castle highlighted the importance of cutting-edge developments in biotechnology. They recognized the need for partnership between various sectors for protecting populations against outbreaks of infectious diseases or terrorist acts.

Executives of Fraunhofer including Prof. Hans-Jörg Bullinger, President of Fraunhofer Gesellschaft, Dr. Dirk Polter, Director, Fraunhofer Gesellschaft, Prof. Dennis Tsichritizis, President of Fraunhofer USA, Inc., Prof. Dr. Rainer Fischer, Senior Executive Director Fraunhofer Institute for Molecular Biology and Applied Ecology, also actively participated in this first Topical Meeting and addressed the participants.

Professor Bullinger, a champion of nurturing and implementing innovations, emphasized the need to accelerate the translation of research into products, especially in pharmaceutical research. He introduced the "**Life Sciences Alliance**", a network of five Fraunhofer Institutes, which aim to harness biotechnology and gene technology for the benefit of medicine, health and the environment. Among the wide range of research topics dealt with in the Alliance, "faster drug development" is regarded by Fraunhofer as one of the challenges for which major technological breakthroughs are expected.

The meeting received wide publicity. On July 14th, an article in The News Journal, "Bio-Terrorism and the Flu Pandemic: Fraunhofer USA's Center for Molecular Biotechnology Gathers Scientists to Discuss Preparedness and Solutions" highlighted the importance of the conference (http://biz.yahoo.com/bw/050714/145643.html?.v=1).







Pictured from top to bottom: James Robertson, Dirk Polter, Fritz Klocke, Judy McKinney-Cherry, Rainer Fischer, Mike Bowman, and Vidadi Yusibov, Hans Jorg Bullinger with Joe DiPinto.
Photo in center: Sen. Tom Carper addressing the luncheon attendees.







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http://www.delawareonline.com/apps/pbcs.dll/article?AID=2005507190330

Can 'biothreats' be defused?

With new pandemic called inevitable, conference focuses on vaccine needs

BY RICHARD SINE / The News Journal

07/19/2005

Standing before an audience of about 100 scientists and entrepreneurs at the Hotel du Pont on Monday, Dr. Nancy Cox showed an image of a virus with a burning fuse attached.

"This is a bomb," said Cox, chief influenza official at the Center for Disease Control. "It's the H5N1 virus waiting to explode."

Speaking at a conference on how to respond to "biothreats"-- contagious diseases spread by nature or terrorism -- Cox predicted that more Asian countries would soon report human cases of the deadly avian influenza known as H5N1. Cambodia, Thailand and Vietnam have reported cases of the flu in humans.

"We are at the greatest risk of having a pandemic than any time since 1968, when the last pandemic occurred," Cox said in an interview after her presentation.

That global pandemic killed about 1 million people. The worst flu outbreak, in 1917, killed more than 20 million people.

One frightening development is that ducks with the virus are not showing symptoms of the flu, Cox said. Those ducks could infect unwitting farmers, and more human cases increase the chance of human-to-human transmission.

Monday's conference focused largely on how to formulate and quickly manufacture vaccines in the face of a flu pandemic or terrorist attack.

Dr. James Robertson, of the British National Institute for Biological Standards, said the H5N1 virus is too virulent to be used in making vaccines. Thanks to new genetics techniques, a milder strain of the virus is now being tested in many countries for use in a vaccine. But it still takes more than six months to manufacture a vaccine for a new strain of flu, he said.

"A pandemic can spread quite extensively in six months," Robertson said, who called another pandemic "inevitable."

Even after a new vaccine is developed, production is limited because the vaccine-making industry is small.

Conference organizer Vidadi Yusibov said the number of large drug companies developing vaccines has dropped from 25 about 15 years ago to five today. Profits on vaccines are low because they are used only once.

That reality was reflected in the attendance at the conference. While small biotech companies were scattered throughout the audience, big drug companies were largely absent.

For academics and biotech entrepreneurs seeking federal grants, Ken Millburne, of the National Institute of Allergy and Infectious Diseases, described the efforts his agency would fund. They include developing vaccines against multiple strains; finding new ways to make vaccines; or finding faster ways to detect new strains.

Currently, most vaccines are made by growing live viruses in chicken eggs. Yusibov's Newark-based Institute, Fraunhofer USA, is developing a vaccine grown in plants. Another new technique grows vaccines in cells kept in a fermenter.

Both methods are potentially safer than the egg-based method, but could also result in less potent vaccines, warned Dr. Charles Penn, head of research at the British Health Protection Agency.

Contact Richard Sine at 324-2878 or rsine@delawareonline.com.

Pictured from top to bottom, left to right: Hans-Jörg Bullinger
Rance Cleaveland
Konstantin Musiychuk with Vadim Mett
Kathleen Schuelke, Dieter Rombach, Erin Simmonds, Frank Herman
Dean Mann, Alan Kross
Shailaja Rabindran, Mike Bowman, Bernard Link
Carol Sabatini

Excerpts from the Center for Disease Control's website:
http://www.cdc.gov/flu/avian/outbreaks/asia.htm

Recent Avian Influenza Outbreaks in Asia

Outbreaks of highly pathogenic avian influenza A (H5N1) occurred among poultry in 8 countries in Asia (Cambodia, China, Indonesia, Japan, Lao, South Korea, Thailand and Vietnam) during late 2003 and early 2004. At that time, more than 100 million birds either died from the disease or were culled...

As of August 5, 2005 , there have been 112 human cases of avian influenza A (H5N1) in Vietnam (90), Thailand (17), Cambodia (4), and Indonesia (1), resulting in 57 deaths reported since January 2004. For more information about H5N1 infections in humans, visit the World Health Organization (WHO) website.

The avian influenza A (H5N1) epizootic outbreak in Asia is not expected to diminish significantly in the short term. It is likely that H5N1 infection among birds has become endemic to the region and that human infections will continue to occur. So far, no sustained human-to-human transmission of the H5N1 virus has been identified, and no evidence for genetic reassortment between human and avian influenza virus genes has been found; however, the epizootic outbreak in Asia poses an important public health threat.

If these H5N1 viruses gain the ability for efficient and sustained transmission between humans, there is little preexisting natural immunity to H5N1 infection in the human population, and an influenza pandemic could result, with high rates of illness and death... Efforts to produce a vaccine that would be effective against this strain of influenza A (H5N1) virus are under way. Vaccine reference virus strains already have been made and provided to manufacturers to produce pilot lots for human clinical trials as well as to produce a larger quantity of H5N1 vaccine, but mass production and availability of such a vaccine is some time off.

Pictured at right:
Orn Adalsteinsson, Dirk Polter and Dennis Tsichritzis

Pictured from top to bottom, left to right: John Hammond with Phillip Berger, Margaret Shillingford, Hong Bi, Natalie Stevenson, Jue Sun and Kristen Lopez
Donald Fraser with Andre Sharon
Joe Miro with Stephanie Ulbrich
Aldo Taglibue with Rainer Fischer and Francois Arcane
Al Matczun with Darrell Galloway and Vidadi Yusibov
William Hartman with Frances Roland-Lee

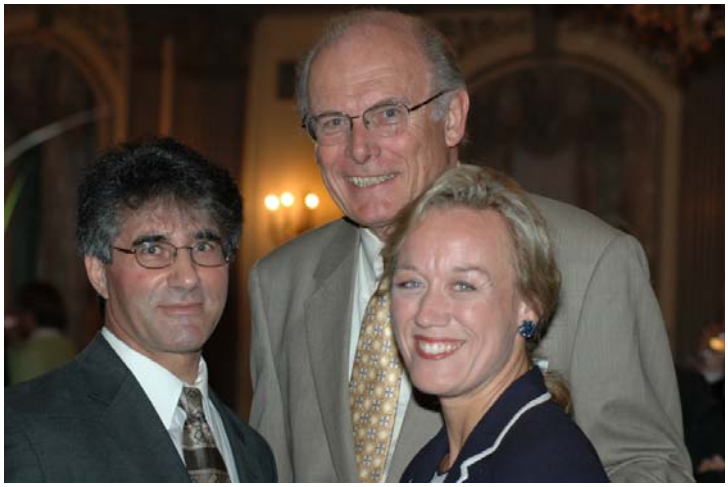







Fraunhofer USA

Fraunhofer USA, Inc. plans to organize future Topical Meetings that will focus on technologies of the Fraunhofer Centers in the U.S. Each of the five Fraunhofer USA research centers is closely affiliated with at least one of the 58 Fraunhofer Institutes in Germany, and also partnered with major research universities in the U.S. Besides Molecular Biotechnology, the other Centers specialize in Laser Technology, Experimental Software Engineering, Coatings and Laser Applications, and Manufacturing Innovation. Fraunhofer USA, Inc. performs applied research under contract to government and industry and is a wholly-owned subsidiary of Fraunhofer-Gesellschaft.



Pictured from left to right: Vidadi Yusibov, William Hartman and Judy McKinney-Cherry.

Thanks to the following companies for sponsoring the social events at this conference.

Delaware Biotechnology Institute

Integrated BioPharma, Inc.

Science Center

Delaware Technology Park

AthenaBio

QPS Quest Pharmaceutical Services

Pictured from top to bottom and left to right:
James Sullivan with Dale Ervin
Erin Logan with Vidadi Yusibov and Dirk Polter
Ramon Jordan with John Hammond
Darrell Galloway, Jennie Hunter-Cevera and Les Baillie
Hazell Reed with Mie Mie Strickler
Ted Poehler with Anke Hellwig
Ray Yin with Gail Chapman
Jennifer Kmiec with Stephanie Ulrich.