NEW Frontiers IN CANCER CELL AND GENE THERAPY

[ THE FIRST DECADE ]

ALLIANCE FOR CANCER GENE THERAPY®
As pioneers forge new ways of life and open new gateways to opportunity, the **ALLIANCE FOR CANCER GENE THERAPY** paves the way for molecular medicine to conquer cancer. Cell and gene-based therapies are the new frontier.

**PROGRESS** is rapid.

**POSSIBILITIES** limitless.

**POTENTIAL** within reach.

Many of the best people in the best places are **AT THE FOREFRONT**.

**We are SO close.**

Simply stated, OUR MISSION is to seek out and support revolutionary scientific research into the causes, treatment and prevention of all types of cancer, using cells and genes as medicine. TO THIS END we fund and monitor studies and trials that meet the highest possible standards, educate the public on the potential, and facilitate greater collaboration among the scientific and philanthropic communities to promote progress.

ACGT is the only charitable organization in the nation **DEDICATED EXCLUSIVELY** to cell and gene-based therapies for cancer.
Cancer is as deadly as ever.

All of us KNOW someone or LOVE someone or have LOST someone to cancer. Cancer is the #1 WORLDWIDE cause of death. IN AMERICA, 1 of 4 will develop cancer at some time. EVERY MINUTE of every day, 2 of us discover we have cancer. 11+ million are LIVING WITH CANCER. 3.5+ million NEW CANCERS are diagnosed EVERY YEAR. 1500 patients DIE EVERY DAY. 1 OF EVERY 4 DEATHS is due to cancer. 2 of 3 survive 5+ years but suffer severely in treatment AND survival does NOT = CANCER FREE. Cancer costs roughly 265 BILLION DOLLARS every year in medical care and lost productivity.

“In 2010, about six hundred thousand Americans, and more than 7 million humans around the world, will die of cancer.”

Siddhartha Mukherjee
2011 Pulitzer Prize Winner
“The Emperor of All Maladies”

Sources:
World Health Organization 2010
American Cancer Society 2010
“Cancer is a ferocious dragon breathing fire throughout the world. Perhaps gene therapy will tame that dragon and make cancer a dinosaur. That would be something.”

Cancer patient, 2007

Cancer is treated as it has been treated for 50+ years.

We know now that cancer is the result of a MUTATED, MISSING, OR DAMAGED GENE. Normal cells know when to stop growing, CANCER CELLS DO NOT. The immune system does not recognize cancer as a threat because it is IN THE DNA. The only way to destroy cancer is to go directly to the cancer. TRADITIONAL TREATMENTS may slow the spread but RARELY STOP THE CANCER completely. SURGERY is contingent on location, size and stage. RADIATION endangers healthy body parts. CHEMOTHERAPY attacks the entire body to get to the cancer.
Targeted therapies will revolutionize cancer care.

Molecular medicine makes it possible to DECIPHER the code, RESET the gene, AWAKEN the immune system, SHUT DOWN tumor life-support, and/or DEPLOY the body's own systems to reject cancers. Cell and gene-based therapies are TARGETED THERAPIES – utilizing a patient's OWN CELLS to do battle with cancer – without damage to other parts of the body.

Drugs can be delivered directly to the tumor to facilitate cancer CELL DEATH. Vaccines can boost the immune system to REJECT AND DESTROY cancers. Cell and gene therapeutics DESTROY CANCER STEM CELLS, believed to be the root of many cancers. Healthy genes injected into the tumor serve as a CATALYST for the body to repair itself. It is possible to STRANGULATE A TUMOR by cutting off its blood supply. In the not so distant future, an inoculation may make it possible to RESIST CANCER.

“Turning the immune system against cancer cells would involve turning the body’s defense mechanisms against a part of itself. Designing a vaccine to do this entails creating the biological version of a stealth weapon encased in a smart bomb equipped with a guided missile.”

Alice Paul
“A Shot at Cancer”
Time Magazine, September 3, 2009
Progress is dramatic and exponential.

OVER 800 TREATMENTS that target specific gene and cell mutations are in development. HUNDREDS of universities and institutions support research into cell and gene-based therapies. THOUSANDS of patients are participating in human trials. HUNDREDS OF STUDIES HAVE BEEN PUBLISHED in the last decade on targeted therapies. PROGRESS REPORTS ARE IN THE NEWS EVERY DAY for almost every form of cancer as well as other diseases. DOZENS of pharmaceutical companies and biotechnology firms are exploring personalized and targeted therapies as alternatives to current cancer treatments. Several drugs have received FDA APPROVAL and others are approved for use in other countries.

“I am optimistic. I see a future in which more cancers are prevented, more are cured and, when not curable, more are managed as effectively as other chronic, lifelong diseases.”

John Mendelsohn, MD, President University of Texas MD Anderson Cancer Center

Please Note: Because statistics in this field change by the moment, we have focused on the order of magnitude rather than the exact numbers. Updates are always available at www.acgtfoundation.org
ACGT promotes progress.

Alliance for Cancer Gene Therapy has AWARDED over $22 million in support of 37 RESEARCH PROJECTS into therapies for brain cancers, breast cancer, leukemia and lymphoma, lymphatic system cancer, lung cancer, metastatic cancers, multiple myeloma, ovarian cancer, prostate cancer, AND neuroblastoma. NEARLY 1,000 esteemed scientists have requested funding. More than 17 RECENT TRIALS are based on ACGT funded laboratory research. 3 patents are pending. More than ONE HUNDRED professional journals cite ACGT as a force for cancer research. In our first decade, we awarded half of our research dollars to DISCOVERY to stimulate innovation and half to ADVANCEMENT to ensure that laboratory success proceeds more rapidly to clinical translation and clinical trials.

“Like all business enterprises, there are disappointments, and like all scientific methods, there are constant challenges to get it right. Now that we’ve charted a new course, we need to stay the course.”

Edward Netter
1933 – 2011

An estimated 1 of 50 cancer patients will enter a clinical trial in the next five years.
ACGT Co-Founder Edward Netter served as President and Board Chair during the first decade of the organization’s life and realized his goal of establishing a force for the future of targeted therapies for cancer. He believed that there is always a better way to do almost anything. He believed in the importance of big ideas. He believed in the power of collaboration. He understood that a charitable foundation must operate at the same level of efficacy as the science. He was broken-hearted when his daughter-in-law succumbed to cancer and he was determined to seek out new treatment alternatives. He never wavered in his faith in cell and gene-based therapies as the new paradigm for cancer care. He inspired others with his vision. He was committed to education as well as medical science. He put his money and his time into what he believed. He was a businessman who approached philanthropy with the same high standards of integrity and efficiency as his numerous successful businesses. In 2006, he was inducted into the Business Leader Hall of Fame at Quinnipiac University School of Business for his enduring contribution to leadership. If there were a Hall of Fame for philanthropy, Edward would be at the head table.
Breakthrough: leukemia cells annihilated.

In August 2011, ACGT Scientific Advisory Council member and Research Fellow, Dr. Carl June, and his team at the University of Pennsylvania Abramson Cancer Center reported stunning results of a human trial using a killer virus to kill leukemia cells. By re-engineering and delivering powerful T-cells within an inactivated HIV virus, tumor cells were largely destroyed. And, in a first-ever response, these “serial killers” remain active and continue to isolate and obliterate other cancer cells that might emerge. While some T-cells decayed, they stayed on alert for as long as 12 months. Trial patients achieved complete remission or more than 70% cancer cell reduction. “Within three weeks, the tumors, which were several pounds each, had been obliterated in a way that was much more complete than we ever expected,” said Dr. June. “This has never been seen – these trial results exceeded our wildest imaginations.”

“It took less than 2 minutes to infuse the cells and I felt fine afterward. However, less than 2 weeks later, I woke up one morning with chills and a fever – I was sure CLL cells were dying. It was about a week after this that I was informed that there was no CLL in my blood – it was working and I was winning. It was another week later that I got the news that my bone marrow was completely free of detectable disease.”

A patient in the University of Pennsylvania CLL trial who, one year later, remains cancer free.

This is one of the first times that a cancer gene therapy drug was developed and used to treat patients, without the support of the NIH or the pharmaceutical industry. The trial was made possible by the university and Alliance for Cancer Gene Therapy.
Potential is within reach.

**Dr. Laurence Cooper**, Children’s Cancer Hospital, MD Anderson Cancer Center, has been developing immune-mediated therapies and CANCER VACCINES to fight leukemia and lymphoma in children. He uses the power of T-cells to redirect the immune system to fight back on behalf of the youngest victims of cancer. **Dr. Thomas Griffith**, University of Minnesota, employs a MOLECULAR CANCER-FIGHTING AGENT to induce cell death without typical side effects. The agent is unique in its ability to influence a wide range of prostate cancer cells, particularly in combination with chemotherapy and/or radiation. **Dr. Carl June**, University of Pennsylvania Abramson Cancer Center, harnesses the power of the immune system to RECOGNIZE AND DESTROY ovarian tumor cells, based on research first conducted on leukemia. The immune system response has resulted in the destruction of tumors entirely. **Dr. Thomas Kipps**, University of California, San Diego, uses a DIRECT INJECTION of a cancer fighting virus into the lymph nodes of patients suffering from Lymphoma/Leukemia, to side-swipe the patient’s resistance to treatment and cause the cancer cells to die.
And within reason.

Dr. Kah-Whye Peng, Mayo Clinic Cancer Center, is using a measles virus to carry life-altering genes to INDUCE CELL DEATH in cancers of many types, with a focus on ovarian cancer, glioma, and multiple myeloma. Dr. Eckhard Podack, University of Miami, has developed a PROTOTYPE VACCINE that facilitates a generation of killer cells to attack non-small cell lung cancer, among the most deadly of all cancers. Dr. Michel Sadelain, Memorial Sloan-Kettering Cancer Center, uses a sophisticated method of CELL ENGINEERING to establish potent and durable immunity to Chronic Lymphocytic Leukemia. Cells are also engineered to express biological markers to track their location and monitor the patient’s response to therapy using non-invasive imaging technology. Dr. Miguel Sena-Esteves, University of Massachusetts Medical School, delivers a CANCER-FIGHTING GENE to normal tissue surrounding brain tumors to keep the cancer from spreading. In early research, the treatment eradicated the tumors completely in mice. Dr. Xianzheng Zhou, University of Minnesota, uses DNA MANIPULATION to express both a therapeutic gene and a reporter gene to fight leukemia – the engineered T-Cells not only kill cancer cells, they produce anti-tumor agents that will protect against cancer in the future.

Many more success stories at www.acgtfoundation.org
ACGT Research Fellows pave the way.

2010
Nabil Ahmed, MD, MPH
Institution: Baylor College of Medicine
Focus: Brain Cancer
Research: Stem Cell Directed Therapy

Glenn Dranoff, MD
Institution: Dana Farber/Harvard Cancer Center
Focus: Leukemia
Research: Immunotherapy

Thomas Kipps, MD, PhD
Institution: Moores Cancer Center, University of California, San Diego
Focus: Lymphoma/Leukemia
Research: Immunotherapy
Award: Recipient of The Swim Across America Investigator Award

Michael Z. Lin, MD, PhD
Institution: Stanford University
Focus: Brain and Breast Cancer
Research: Tumor Specific Replicating Viruses and Bacteria

2009
Steve Thorne, PhD
Institution: University of Pittsburgh
Focus: Breast & Ovarian Cancers
Research: Tumor Specific Replicating Viruses & Bacteria

2008
Carl June, MD
Institution: University of Pennsylvania Abramson Family Cancer Research Institute
Focus: Ovarian Cancer
Research: Immune-mediated Gene Therapy
Award: Recipient of The Joan Miller & Linda Bernstein Gene Therapy Ovarian Cancer Award

Antonio E. Chiocca, MD, PhD
Institution: Ohio State University Research Foundation
Focus: Glioma
Research: Tumor Specific Replicating Viruses & Bacteria

Ronald Levy, MD
Institution: Stanford University
Focus: Lymphoma
Research: Immune-mediated Gene Therapy & Cancer Vaccines

Clodagh O’Shea, PhD
Institution: Salk Institute for Biological Studies
Focus: Breast Cancer
Research: Tumor Specific Replicating Viruses & Bacteria

Khalid Shah, PhD
Institution: Harvard Medical School, Massachusetts General Hospital
Focus: Brain Cancer
Research: Tumor Targeting
Award: Recipient of The Swim Across America Young Investigator Award

2007
Robert Cattaneo, PhD
Institution: Mayo Clinic College of Medicine
Focus: Lymphoma/Leukemia
Research: Tumor Specific Replicating Viruses & Bacteria

George Coukos, MD, PhD
Institution: University of Pennsylvania Abramson Family Cancer Research Institute
Focus: Ovarian & Peritoneal Cancer
Research: Anti-angiogenesis
Award: Recipient of The Dr. Judah Folkman Angiogenesis Award for Cancer Gene Therapy

Maciej S. Lesniak, MD
Institution: University of Chicago
Focus: Brain Cancer
Research: Tumor Targeting & Vector Development

Kah-Whye Peng, PhD
Institution: Mayo Clinic Cancer Center
Focus: Myeloma
Research: Tumor Specific Replicating Viruses & Bacteria

Eckhard Podack, MD, PhD
Institution: University of Miami Miller School of Medicine
Focus: Lung Cancer
Research: Immune-mediated Gene Therapy

Harald Sauthoff, MD
Institution: New York University
Focus: Breast/Lung Cancer
Research: Tumor Targeting & Vector Development

“ACGT has created an army of investigators.”
George Coukos, MD, PhD
University of Pennsylvania, Abramson Family Cancer Research Institute, ACGT Research Fellow 2006
<table>
<thead>
<tr>
<th>Year</th>
<th>Name</th>
<th>Institution</th>
<th>Focus</th>
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<tbody>
<tr>
<td>2005</td>
<td>Biao He, PhD</td>
<td>University of Georgia</td>
<td>Breast Cancer</td>
<td>Tumor Specific Replicating Viruses &amp; Bacteria</td>
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<td></td>
<td>Thomas J. Kipps, MD, PhD</td>
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<td>Hyam I. Levitsky, MD</td>
<td>Johns Hopkins University School of Medicine</td>
<td>Lymphoma/Leukemia</td>
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<td>Miguel Sena-Esteves, PhD</td>
<td>University of Massachusetts Medical School</td>
<td>Brain Cancer</td>
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<td>Koji Tamada, MD, PhD</td>
<td>University of Maryland</td>
<td>Lymphatic Systems</td>
<td>Immune-mediated Gene Therapy</td>
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<td>Xianzheng Zhou, MD, PhD</td>
<td>University of Minnesota – Twin Cities</td>
<td>Blood, Lymphoma/Leukemia</td>
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<td>Yiping Yang, MD, PhD</td>
<td>Duke University</td>
<td>Lymphoma/Leukemia</td>
<td>Immunotherapy</td>
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<td>2004</td>
<td>Chien-Fu Hung, PhD</td>
<td>Johns Hopkins University School of Medicine</td>
<td>Ovarian Cancer</td>
<td>Immunotherapy</td>
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<td>Mukesh Jain, MD, FAHA</td>
<td>Case Western Reserve University</td>
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<td>Anti-angiogenesis</td>
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<td>Carl H. June, MD</td>
<td>University of Pennsylvania Abramson Family Cancer Research Institute</td>
<td>Lymphoma/Leukemia</td>
<td>Immune-mediated Gene Therapy</td>
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<td></td>
<td>Suzie Pun, PhD</td>
<td>University of Washington</td>
<td>Metastatic Cancer</td>
<td>Targeted Non-Viral Delivery</td>
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<td>Michel Sadelain, MD, PhD</td>
<td>Memorial Sloan-Kettering Cancer Center</td>
<td>Lymphoma/Leukemia</td>
<td>Recipient of The Patricia Zoch Tate Gene Therapy Award</td>
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<td>Jian Yu, PhD</td>
<td>University of Pittsburgh School of Medicine, Hillman Cancer Center</td>
<td>Lung Cancer</td>
<td>Oncogenesiss</td>
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<td>Laurence Cooper, MD, PhD</td>
<td>University of Texas, MD Anderson Cancer Center</td>
<td>Breast Cancer</td>
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<td>Timothy Lane, PhD</td>
<td>University of California, Los Angeles</td>
<td>Anti-angiogenesis</td>
<td>Recipient of The Kimberly Lawrence Netter Gene Therapy Breast Cancer Award</td>
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<td>Todd R. Reilly, PhD</td>
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<td>Katherine Ryman, PhD</td>
<td>University of Pittsburgh, Center for Vaccine Research</td>
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<td>Tumor Specific Replicating Viruses</td>
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<td>Robert Vonderheide, MD, D.Phil.</td>
<td>University of Pennsylvania Abramson Family Cancer Research Institute</td>
<td>Neuroblastoma</td>
<td>Immune-mediated Gene Therapy</td>
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<td>2002</td>
<td>Jeffrey S. Bartlett, PhD</td>
<td>The Research Institute at the National Children's Hospital</td>
<td>Ovarian Cancer</td>
<td>Vector Development</td>
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<td>Andrew M. Davidoff, MD</td>
<td>St. Jude Children's Research Hospital</td>
<td>Neuroblastoma</td>
<td>Anti-angiogenesis</td>
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<td></td>
<td>Thomas S. Griffith, PhD</td>
<td>University of Minnesota</td>
<td>Prostate Cancer</td>
<td>Immune-mediated Gene Therapy</td>
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</table>
Nanoparticles search and destroy cancer cells.

In the spring of 2010, Maria Escalera traveled 5,000 miles to participate in a clinical trial to save her life from Stage 4 lung cancer. Diagnosed four years earlier, the cancer had spread to her pancreas and liver. This was her last hope. She arrived from Venezuela at MD Anderson Cancer Center in Texas for treatment with a drug called FUS1 nanoparticle, which locates and penetrates cancer cells using a novel delivery method. The result: Escalera has a new lease on life.

ACGT Scientific Advisory Council member, Dr. Jack Roth, one of the lead scientists in the development of this miracle drug, has followed the progress of all those testing the drug’s safety and efficacy and is thus one of Escalera’s guardian angels. “They call me their miracle patient,” she said following the trial. One of many, and many more to come.
Extraordinary possibilities = great challenges.

In the SHORT-TERM, targeted therapies will augment traditional treatments for greater effect. LONGER-TERM, medicines and vaccines will attack and destroy tumors and inhibit their growth potential. IN THE FUTURE, cell and gene-based therapies have the potential to make cancer a manageable disease – in effect, a permanent remission. SOMEDAY, sooner than you might imagine, vaccines will inoculate us against cancer, preventing the disease from ever happening. FURTHERMORE, since cell and gene-based therapies have application to chronic diseases like cystic fibrosis, hemophilia, macular degeneration, muscular dystrophy and Parkinson’s, the research today has potentially enormous impact tomorrow. The ULTIMATE GOAL is to render cancer a disease of the past.

The FUTURE of cell and gene-based therapies depends on a few critical factors: Increased FUNDING for research. Greater ATTENTION from both government and private sectors. Better ACCESS to manufacturing capacity. Advanced TECHNOLOGY. A streamlined APPROVALS process for clinical trials and ultimately medical practice. INVESTMENT by the biomedical and pharmaceutical industry. Will. TENACITY. Perseverance. Continued FAITH in the extraordinary science.

“Our team has been working on gene therapy for 20 years, and the last 10 years we also have been perfecting using tiny hollow spheres – called nanoparticles – as a new way to deliver the drug to patients whose cancer has spread. Seeing them benefit from our efforts after so many years is extremely rewarding.”

Jack Roth, MD, Director, W. M. Keck Center for Innovative Cancer Therapies, MD Anderson Cancer Center
150+ institutions in North America are investigating gene therapies.
Seven years after gene therapy: alive and well.

In 2002, Bunny Morrow of Texas was diagnosed with lung cancer so advanced it had wrapped around her vocal chords. Given the spread of the cancer and positive lymph nodes, surgery was not a good option, although four years later, her upper left lobe was removed and she underwent chemotherapy in order to participate in a gene therapy trial at Mary Crowley Oncology Center at Baylor University. Cancer cells were removed and irradiated, and injected back into her body to stimulate her immune system. “I had about 16 injections and absolutely no side effects beyond a couple of allergic reactions... no problem,” she said.

Now, five years later, at age 77, Bunny is going strong. She recently had her annual PET scan and she remains tumor free. Other than residual damage to her vocal chords that often finds her hoarse, she says she feels great and she’s happy to shout the praises of gene therapy. “Thank God I was able to be in that trial.”

“It is by now accepted by a large number in the community that killer cells are really the primary weapon against cancer if the immune system is involved.”

Eckhard Podack, MD, PhD
University of Miami, Miller School of Medicine
ACGT Research Fellow – Lung Cancers
ACGT: a decade of progress

2001  Alliance for Cancer Gene Therapy founded by Barbara and Edward Netter
      Scientific Advisory Council formed

2002  First three grant awards focus on discovery

2003  Five grants awarded to encourage innovative research

2004  Six grants awarded including two for clinical translation
      ACGT presents “An Editor’s Roundtable” in NYC

2005  Seven grants awarded

2006  Six grants awarded
      Fifth Anniversary dinner presents Lifetime Achievement Award
      to Dr. Judah Folkman

2007  Four grants awarded including two for clinical translation
      Swim Across America launches first annual event for ACGT

2008  Gene Therapy Ovarian Cancer grant awarded
      Educational forum on the state of gene therapy for the treatment of
      lung cancer

2009  One Young Investigator grant awarded
      Educational panel on breast cancer co-hosted with
      Breast Cancer Alliance, Greenwich Hospital and Greenwich Library
      Educational forum on new cell and gene treatments for lymphoma, leukemia
      and prostate cancer
      Educational forum on promise of gene therapy for the treatment of
      breast cancer

2010  ACGT cited frequently in the media as a facilitator for gene therapy research
      Four grants awarded
      Educational forum on cell and gene therapy for brain cancer
      Gala Cocktail Benefit celebrating progress honors ACGT research scientists
      Educational forum on cell/gene therapy for pediatric cancers

2011  5th Annual Swim Across America benefits ACGT
ACGT Leadership
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New York, NY

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Massachusetts General Hospital
Boston, MA

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Yale Cancer Center
New Haven, CT

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Astellas Pharma
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Harvard Medical School
Boston, MA

A. Dusty Miller, PhD
Fred Hutchinson Cancer Center
University of Washington
Seattle, WA

John Nemunaitis, MD
Mary Crowley Medical Research Centers
Dallas, TX

Drew Pardoll, MD, PhD
Sidney Kimmel Cancer Center
Johns Hopkins University
School of Medicine
Baltimore, MD

Jack Roth, MD, FACS
University of Texas M.D. Anderson Cancer Center
Houston, TX

Stephen J. Russell, MD, PhD
Mayo Clinic
Rochester, MN

Michel Sadelain, MD, PhD
Memorial Sloan-Kettering Cancer Center
New York, NY

Thomas J. Wickham, PhD
Merrimack Pharmaceuticals
Cambridge, MA

George D. Yancopoulos, MD, PhD
Regeneron Pharmaceuticals, Inc.
Tarrytown, NY

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In Memoriam
Edward Netter
Founding President (2001-2011)

Progress Report created by Randy Kraft/Writer4Hire and Kathryn Ford/Ford Design Group, Inc.
“Do we have a cure yet? No. But great progress has been made, and we have firmly positioned this organization to continue to be the driving force for progress in the future. We are more than optimistic; we are confident that cancer gene therapies are moving towards a tipping point, and that someday, sooner rather than later, cancer will be treated with far greater odds for success and less toxicity to the patient.”

Edward Netter, Co-Founder, Alliance for Cancer Gene Therapy

The letters A [Adenine], C [Cytosine], G [Guanine] and T [Thymine] make up the genetic code.