October 27, 2004

Senator John F. Kerry
John Kerry for President
901 15th Street NW
Suite 700
Washington DC 20005

Dear Senator Kerry,

Recently you have made the promotion of embryonic stem cell research, including the cloning of human embryos for research purposes, into a centerpiece of your campaign. You have said you will make such research a "top priority" for government, academia and medicine (Los Angeles Times, 10/17/04). You have even equated support for this research with respect for "science," and said that science must be freed from "ideology" to produce miracle cures for numerous diseases.

As professionals trained in the life sciences we are alarmed at these statements.

First, your statements misrepresent science. In itself, science is not a policy or a political program. Science is a systematic method for developing and testing hypotheses about the physical world. It does not "promise" miracle cures based on scanty evidence. When scientists make such assertions, they are acting as individuals, out of their own personal faith and hopes, not as the voice of "science". If such scientists allow their individual faith in the future of embryonic stem cell research to be interpreted as a reliable prediction of the outcome of this research, they are acting irresponsibly.

Second, it is no mere "ideology" to be concerned about the possible misuse of humans in scientific research. Federal bioethics advisory groups, serving under both Democratic and Republican presidents, have affirmed that the human embryo is a developing form of human life that deserves respect. Indeed you have said that human life begins at conception, that fertilization produces a "human being." To equate concern for these beings with mere "ideology" is to dismiss the entire history of efforts to protect human subjects from research abuse.

Third, the statements you have made regarding the purported medical applications of embryonic stem cells reach far beyond any credible evidence, ignoring the limited state of our knowledge about embryonic stem cells and the advances in other areas of research that may render use of these cells unnecessary for many applications. To make such exaggerated claims, at this stage of our knowledge, is not only scientifically irresponsible – it is deceptive and cruel to millions of patients and their families who hope desperately for cures and have come to rely on the scientific community for accurate information.

What does science tell us about embryonic stem cells? The facts can be summed up as follows:

- At present these cells can be obtained only by destroying live human embryos at the blastocyst (4-7 days old) stage. They proliferate rapidly and are extremely versatile, ultimately

capable (in an embryonic environment) of forming any kind of cell found in the developed human body. Yet there is scant scientific evidence that embryonic stem cells will form normal tissues in a culture dish, and the very versatility of these cells is now known to be a disadvantage as well – embryonic stem cells are difficult to develop into a stable cell line, spontaneously accumulate genetic abnormalities in culture, and are prone to uncontrollable growth and tumor formation when placed in animals.

• Almost 25 years of research using mouse embryonic stem cells have produced limited indications of clinical benefit in some animals, as well as indications of serious and potentially lethal side-effects. Based on this evidence, claims of a safe and reliable treatment for any disease in humans are premature at best.

• Embryonic stem cells obtained by destroying cloned human embryos pose an additional ethical issue – that of creating human lives solely to destroy them for research – and may pose added practical problems as well. The cloning process is now known to produce many problems of chaotic gene expression, and this may affect the usefulness and safety of these cells. Nor is it proven that cloning will prevent all rejection of embryonic stem cells, as even genetically matched stem cells from cloning are sometimes rejected by animal hosts. Some animal trials in research cloning have required placing cloned embryos in a womb and developing them to the fetal stage, then destroying them for their more developed tissues, to provide clinical benefit – surely an approach that poses horrific ethical issues if applied to humans.

• Non-embryonic stem cells have also received increasing scientific attention. Here the trajectory has been very different from that of embryonic stem cells: Instead of developing these cells and deducing that they may someday have a clinical use, researchers have discovered them producing undoubted clinical benefits and then sought to better understand how and why they work so they can be put to more uses. Bone marrow transplants were benefiting patients with various forms of cancer for many years before it was understood that the active ingredients in these transplants are stem cells. Non-embryonic stem cells have been discovered in many unexpected tissues – in blood, nerve, fat, skin, muscle, umbilical cord blood, placenta, even dental pulp – and dozens of studies indicate that they are far more versatile than once thought. Use of these cells poses no serious ethical problem, and may avoid all problems of tissue rejection if stem cells can be obtained from a patient for use in that same patient. Clinical use of non-embryonic stem cells has grown greatly in recent years. In contrast to embryonic stem cells, adult stem cells are in established or experimental use to treat human patients with several dozen conditions, according to the National Institutes of Health and the National Marrow Donor Program (Cong. Record, September 9, 2004, pages H6956-7). They have been or are being assessed in human trials for treatment of spinal cord injury, Parkinson's disease, stroke, cardiac damage, multiple sclerosis, and so on. The results of these experimental trials will help us better assess the medical prospects for stem cell therapies.

• In the case of many conditions, advances are likely to come from sources other than any kind of stem cell. For example, there is a strong scientific consensus that complex diseases such as Alzheimer's are unlikely to be treated by any stem cell therapy. When asked recently why so many people nonetheless believe that embryonic stem cells will provide a cure for Alzheimer's disease, NIH stem cell expert Ron McKay commented that "people need a fairy tale" (Washington Post, June 10, 2004, page A3). Similarly, autoimmune diseases like juvenile

diabetes, lupus and MS are unlikely to benefit from simple addition of new cells unless the underlying problem – a faulty immune system that attacks the body's own cells as though they were foreign invaders – is corrected.

In short, embryonic stem cells pose one especially controversial avenue toward understanding and (perhaps) someday treating various degenerative diseases. Based on the available evidence, no one can predict with certainty whether they will ever produce clinical benefits – much less whether they will produce benefits unobtainable by other, less ethically problematic means.

Therefore, to turn this one approach into a political campaign – even more, to declare that it will be a "top priority" or receive any particular amount of federal funding, regardless of future evidence or the usual scientific peer review process – is, in our view, irresponsible. It is, in fact, a subordination of science to ideology.

Because politicians, biotechnology interests and even some scientists have publicly exaggerated the "promise" of embryonic stem cells, public perceptions of this avenue have become skewed and unrealistic. Politicians may hope to benefit from these false hopes to win elections, knowing that the collision of these hopes with reality will come only after they win their races. The scientific and medical professions have no such luxury. When desperate patients discover that they have been subjected to a salesman's pitch rather than an objective and candid assessment of possibilities, we have reason to fear a public backlash against the credibility of our professions. We urge you not to exacerbate this problem now by repeating false promises that exploit patients' hopes for political gain.

Signed,*

Rodney D. Adam, M.D.
Professor of Medicine and
Microbiology/Immunology
University of Arizona College of Medicine

Michael J. Behe, Ph.D.
Professor of Biological Sciences
Lehigh University

Thomas G. Benoit, Ph.D.
Professor and Chairman of Biology
McMurry University
Abilene, Texas

David L. Bolender, Ph.D.
Department of Cell Biology,
Neurobiology and Anatomy
Medical College of Wisconsin

Daniel L. Burden, Ph.D.
Assistant Professor of Chemistry
Wheaton College

William J. Burke, M.D., Ph.D.
Professor in Neurology
Associate Professor in Medicine
Associate Professor in Neurobiology
Saint Louis University Medical Center

Mark W. Burket, M.D.
Professor of Medicine
Division of Cardiology
Medical College of Ohio

W. Malcolm Byrnes, Ph.D.
Assistant Professor
Department of Biochemistry and Molecular
Biology
Howard University College of Medicine

Steven Calvin, M.D.
Assistant Professor of OB/GYN and
Women's Health
Co-Chair, Program in Human Rights in
Medicine
University of Minnesota School of Medicine

* Affiliations listed for identification purposes only and do not imply institutional endorsement.

James Carroll, M.D.
Professor of Neurology, Pediatrics, and Biochemistry and Molecular Biology
Medical College of Georgia

John R. Chaffee, M.D.
Assistant Clinical Professor
Department of Family Medicine
University of Washington

Robert Chasuk, M.D.
Clinical Assistant Professor
Department of Family Medicine
Tulane University

William P. Cheshire, Jr., M.D.
Associate Professor of Neurology
Mayo Clinic

Richard A. Chole, M.D., Ph.D.
Professor and Head of Otolaryngology
Washington University in St. Louis
School of Medicine

Maureen L. Condic, Ph.D.
Associate Professor
Department of Neurobiology and Anatomy
University of Utah School of Medicine

Keith A. Crist, Ph.D.
Associate Professor
Department of Surgery
Medical College of Ohio

Keith A. Crutcher, Ph.D.
Professor
Department of Neurosurgery
University of Cincinnati Medical Center

Frank Dennehy, M.D., FAAFP
Assistant Clinical Professor of Family Medicine
Virginia Commonwealth University

Kenneth J. Dormer, M.S., Ph.D.
Professor of Physiology
University of Oklahoma College of Medicine

Lawrence W. Elmer, M.D., Ph.D.
Associate Professor, Dept. of Neurology
Director, Parkinson's Disease and Movement Disorder Program
Medical Director, Center for Neurological Disorders
Medical College of Ohio

Kevin T. FitzGerald, SJ, Ph.D., Ph.D.
David P. Lauler Chair in Catholic Health Care Ethics
Research Associate Professor
Department of Oncology
Georgetown University Medical Center

Raymond F. Gasser, Ph.D.
Professor
Department of Cell Biology and Anatomy
Louisiana State University School of Medicine

Hans Geisler, M.D.
Clinical Professor of Obstetrics and Gynecology
Indiana University Medical Center

Donald A. Godfrey, Ph.D.
Professor of Otolaryngology
Department of Surgery
Medical College of Ohio

Samuel Hensley, M.D.
Assistant Clinical Professor
School of Medicine
University of Mississippi

David C. Hess, M.D.
Professor and Chairman
Department of Neurology
Medical College of Georgia

Paul J. Hoehner, M.D., MA, Ph.D., FAHA
Associate Professor
Department of Anesthesiology
The University of Virginia School of Medicine

C. Christopher Hook, M.D.
Consultant in Hematology and Internal Medicine
Assistant Professor of Medicine
Mayo Clinic College of Medicine

* Affiliations listed for identification purposes only and do not imply institutional endorsement.

Elizabeth A. Johnson, M.D.
Consultant, Hematology/Oncology
Mayo Clinic Jacksonville
Assistant Professor of Oncology
Mayo Clinic College of Medicine

Nancy L. Jones, Ph.D.
Associate Professor of Pathology
Wake Forest University School of Medicine

C. Ward Kischer, Ph.D.
Emeritus Professor
Cell Biology and Anatomy
Specialty in Human Embryology
University of Arizona College of Medicine

Kirsten J Lampi, M.S., Ph.D.
Associate Professor of Integrative Biosciences
School of Dentistry
Oregon Health Sciences University

John I. Lane, M.D.
Assistant Professor of Radiology
Mayo Clinic School of Medicine

David L. Larson, M.D.
Professor and Chairman
Department of Plastic Surgery
Medical College of Wisconsin

Micheline Mathews-Roth, M.D.
Associate Professor of Medicine
Harvard Medical School

Roger R. Markwald, Ph.D.
Professor and Chair
Department of Cell Biology and Anatomy
Medical University of South Carolina

Victor E. Marquez, Ph.D.
Chief, Laboratory of Medicinal Chemistry
Center for Cancer Research
National Cancer Institute
Frederick, Maryland

Ralph P. Miech, M.D., Ph.D.
Associate Professor Emeritus
Department of Molecular Pharmacology,
Physiology & Biotechnology
Brown University School of Medicine

Mary Ann Myers, M.D.
Associate Professor
Medical College of Ohio

Rimas J. Orentas, Ph.D.
Associate Professor of Pediatrics
Hematology-Oncology Section
Medical College of Wisconsin

Robert D. Orr, M.D., CM
Clinical Ethicist and Professor
University of Vermont College of Medicine

Jean D. Peduzzi-Nelson, Ph.D.
Research Associate Professor
Department of Visual Sciences
University of Alabama at Birmingham

Edmund D. Pellegrino, M.D.
Emeritus Professor
Medicine and Medical Ethics
Center for Clinical Bioethics
Georgetown University Medical Center

John A. Petros, M.D.
Associate Professor
Urology and Pathology
Emory University

David A. Prentice, Ph.D.
Affiliated Scholar
Center for Clinical Bioethics
Georgetown University Medical Center

Paul J. Ranalli, M.D., FRCPC
Lecturer, Division of Neurology
Department of Medicine
University of Toronto

John F. Rebhun, Ph.D.
Adjunct Scientist
Indiana University School of Medicine

Leonard P. Rybak, M.D., Ph.D.
Professor of Surgery
Southern Illinois University School of Medicine

Dwayne D. Simmons, Ph.D.
Director, Inner Ear Research Core Center
Department of Otolaryngology
Washington University School of Medicine

* Affiliations listed for identification purposes only and do not imply institutional endorsement.

Joseph B. Stanford, M.D., MSPH
Associate Professor
Family and Preventive Medicine
University of Utah

John M. Templeton, Jr., M.D., FACS
Adjunct Professor of Pediatric Surgery
University of Pennsylvania School of Medicine

Claire Thuning-Roberson, Ph.D.
Vice President
Product Development and Compliance
Sunol Molecular Corporation
Miramar, Florida

Anton-Lewis Usala, M.D.
Chief Executive Officer and Medical Director
Clinical Trial Management Group
Greenville, North Carolina

Richard A. Watson, M.D.
Professor of Urologic Surgery
The University of Medicine and Dentistry of New Jersey Medical School

Dennis D. Weisenburger, M.D.
Director of Hematopathology
Dept of Pathology and Microbiology
University of Nebraska School of Medicine

H. Joseph Yost, Ph.D.
Professor of Oncological Sciences
University of Utah

Joseph R. Zanga, M.D., FAAP, FCP
President, American College of Pediatricians
Professor of Pediatrics
Brody School of Medicine
East Carolina University

* Affiliations listed for identification purposes only and do not imply institutional endorsement.