



**E. R. ZUMWALT, JR.**  
ADMIRAL, U.S. NAVY (RET.)

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DATE: August 6, 1998

TO: Dr. Robert Hartzman  
Naval Medical Research Institute  
Bill Young DoD Marrow Program

FAX NUMBER:

FROM: Admiral Zumwalt

TOTAL NUMBER OF PAGES INCLUDING THIS COVER SHEET: 4

**ADMIRAL ZUMWALT & CONSULTANTS, INC.**

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E. R. ZUMWALT, JR.  
PRESIDENT

**FACSIMILE TRANSMISSION**

From the Office of E. R. Zumwalt, Jr.  
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E-MAIL: 103737.1466@compuserve.com

DATE: September 11, 1998

TO: Dr. Howe/Dianne

FAX NUMBER:

FROM: Priscilla

TOTAL NUMBER OF PAGES INCLUDING THIS COVER SHEET: 5

Here is some background information for the meeting on Wednesday, Sept 16 at 4pm in the conference room at Cong Young's office (2407 Rayburn).

Dr. Mangano initiated a visit with Admiral Zumwalt a few weeks ago. His company has an interesting theory for locating previously undetectable cancerous stem cells. He came back yesterday with Mr. Fishbein. In the meantime, he has spoken with Dr. Hartzman as Admiral Zumwalt requested.

Attendees for Sept 16 mtg: Howe, Zumwalt, Mangano, Fishbein (Hartzman invited; unable to attend)

# **STATEMENT OF MANAGERS LANGUAGE**

## **DOD FY 1999 APPROPRIATIONS CONFERENCE**

### **EXCEL STEM CELL PROJECT**

The conferees urge the Department of Defense to give strong consideration to the potential benefits, both military and civilian, offered by the EXCEL Stem Cell program during its evaluation process. The \$7,000,000 needed by the EXCEL program in FY 1999 would ready the technology for clinical trials and provide the nation with a new and aggressive treatment for individuals exposed to weapons of mass destruction (WMD). In addition, EXCEL is likely to benefit a third of the nearly 600,000 Americans who fall victim to cancer each year.

The conferees note the urgent need to develop therapies, like EXCEL, with the potential to repair the body's damaged immune system. The conferees call upon the Army's Breast Cancer program, DARPA, BMDO, agencies developing approaches to WMD defense and other DoD programs with medical missions, to work together to support the EXCEL effort. The conferees strongly encourage the Department to include a request for EXCEL funding in the President's FY 2000 budget submission.

# Science Research Laboratory, Inc.

September 17, 1998

15 WARD STREET  
SOMERVILLE, MA 02143  
FAX (617) 547-4104  
(617) 547-1122

Admiral Elmo Zumwalt  
1000 Wilson Blvd., Suite 3105  
Arlington, VA 22209



Dear Admiral Zumwalt:

I want to take this opportunity to thank you for your introduction to Dr. Craig Howe and Dr. Robert Hartzman yesterday during the reception in the Rayburn House Office Building for Congressman Bill Young and the Bone Marrow Foundation.

We were greatly encouraged by the interest shown by both Drs. Howe and Hartzman in the EXCEL program and by their appreciation of the potential of this new and revolutionary technology for the treatment of cancer. Dr. Hartzman said he saw value in our development program and felt that the research could lead to a significant new understanding of the mechanisms that give rise to cancer. Dr. Howe welcomed our research approach and offered to convey to you his opinions of our approach after due consideration.

As you know, time is growing short, with the conference on the FY 1999 DoD Appropriations bill due to commence in just over a week. Little time is left to us to obtain Chairman Young's commitment to seek an earmark in the conference report for EXCEL.

It is for this reason, and in light of the positive initial assessments by Drs. Howe and Hartzman, that I would like to respectfully ask for your support in making a personal appeal to the Chairman. For your convenience, I have taken the liberty of preparing a draft letter which you may wish to consider sending to Chairman Young along with the attached enclosures. I have tried to fairly represent the views of Drs. Howe and Hartzman and would suggest that you may wish to speak directly with them to clarify their assessments of the project.

Lastly, we had the opportunity yesterday to provide an extensive briefing on EXCEL to Mr. Gregory Lankler, Legislative Director to Chairman Young. He appeared very interested in our technology and indicated that he would be speaking with Chairman Young and you for guidance on how to proceed.

Once again, on behalf of Science Research Laboratory and the EXCEL development team, you have my deepest gratitude for your time and commitment to our effort and to the larger fight against cancer. If possible, I would very much like the opportunity to speak with you tomorrow, Friday the 19th, to elicit your suggestions on what further steps should be taken with conference about to commence.

Sincerely,

  
Joseph Mangano, Ph.D.

BARBARA ANN  
**KARMANOS**  
 CANCER INSTITUTE

September 14, 1998

Executive Office

The Honorable Bill Young  
 Chairman  
 National Security Appropriations subcommittee  
 U.S. House of Representatives  
 H-149 U.S. Capitol  
 Washington, D.C. 20515

Dear Chairman Young:

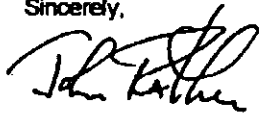
We are writing to commend you for your leadership in the fight against cancer and to ask for your urgent assistance in providing support for the EXCEL Stem Cell project. The need for this technology is immediate and its potential contribution in several specialties concerned with cancer treatment and patient care is far-reaching.

As you know, the Karmanos Cancer Institute is on the front line in the development and clinical testing of high-dose treatments with stem cell support. The EXCEL method has great potential for purging cancer cells from bone marrow transplants and is particularly applicable to treating cancers of the breast, lung, prostate and bone marrow. It does this by assisting the rapid isolation, concentration, and reintroduction of stem cells critical to the reconstitution of the immune system.

A preliminary evaluation of the EXCEL technology by the Drug Discovery Program at the Karmanos Cancer Institute has identified another potentially important application of EXCEL technology to the study and treatment of cancer. This program is eager to test, evaluate, and eventually employ the pulsed-electric field technique at the heart of the EXCEL process to discover new anticancer drugs that selectively kill cancer stem cells and leave normal stem cells unaffected. This innovative technology has the potential to revolutionize the discovery of curative anticancer drugs. Thus, EXCEL would not only hasten the recovery of large numbers of cancer patients after transplantation, but also stimulate the discovery of much better anticancer drugs and new medical technologies.

On behalf of the Karmanos Cancer Institute, we would like to thank you for your commitment to the cause of cancer treatment. EXCEL technology has potentially large medical returns on investment, and we ask that you give every consideration to assisting in the advancement and funding of this innovative technology.

Sincerely,



John D G Rather, PhD  
 Special Assistant to the President,  
 Innovation & Development



Charles K Grieshaber, PhD  
 Director, Drug Discovery



Ralph E Parchment, PhD  
 Clinical Pharmacology



A United Way  
 Agency

Westa Clinical Cancer Center  
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 Detroit, Michigan 48201  
 (313) 993-7770  
 (313) 993-7145 (Fax)  
<http://www.kci.wayne.edu>

Michigan Cancer Foundation  
 The Detroit Medical Center  
 Wayne State University



Meyer I. Prentis  
 Comprehensive Cancer Center of  
 Metropolitan Detroit —  
 A Comprehensive Cancer Center Designated by  
 the National Cancer Institute

# DRAFT

The Honorable Bill Young  
Chairman  
National Security Appropriations subcommittee  
U.S. House of Representatives  
H-149 U.S. Capitol  
Washington, D.C. 20515

Dear Bill:

I am writing to strongly urge that you support efforts to fund the EXCEL Stem Cell program when conference deliberations commence on the FY 1999 Department of Defense Appropriations bill.

This is a most meritorious research effort which I believe could contribute significantly to the development of new drug therapies for cancer patients. It also could serve as a treatment method for individuals whose immune system has been adversely affected by exposure to nuclear, biological or chemical weapons.

**Funding in the amount of \$7 million is urgently needed to prepare EXCEL for clinical trials, a process which will take about 18 months. I would be most grateful if these funds could be specifically earmarked in the conference report, perhaps from the funds made available for Medical Research and Development programs.** If not, I would be grateful if you would include the attached language in the Statement of Managers encouraging the DoD to give strong consideration to funding the program next year.

You may be aware that the Senate listed EXCEL in its committee report as one of the programs which it recommended be funded by DoD next year from the amount provided in the medical R&D account. However, no specific amount was suggested for EXCEL, leaving open the possibility that this most worthwhile program might not be funded.

I am also enclosing a copy of a recent letter sent to you from senior researchers at the Karmanos Cancer Institute attesting to the importance of continuing to pursue the development of EXCEL technology. Karmanos is one of our nation's foremost cancer research institutions and is slated to be a principal participant in the EXCEL clinical trials.

I understand that both your personal and subcommittee staffs have received favorable reports on the EXCEL program. I have discussed EXCEL with Dr. Bob Hartzman who regards it as a promising new approach to cancer treatment and one which is deserving of continued, aggressive research. He was encouraged by early laboratory results which suggest that the technology could provide medical researchers with a fundamentally new insight into the mechanism which triggers the onset of many cancers. This, of course, would be of profound benefit to our work at the Bone Marrow Foundation.

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Additionally, I am informed that Dr. Craig Howe was briefed on EXCEL by members of the development team and was favorably impressed with its potential. I will encourage him to convey his assessment directly to your office.

As always, I remain deeply appreciative of your commitment to our bone marrow registry effort and of your willingness to support cutting edge research into new lifesaving cancer treatments. EXCEL is one such approach.

Thank you in advance for considering this request. I will contact you shortly to follow-up.

Sincerely,

# **STATEMENT OF MANAGERS LANGUAGE**

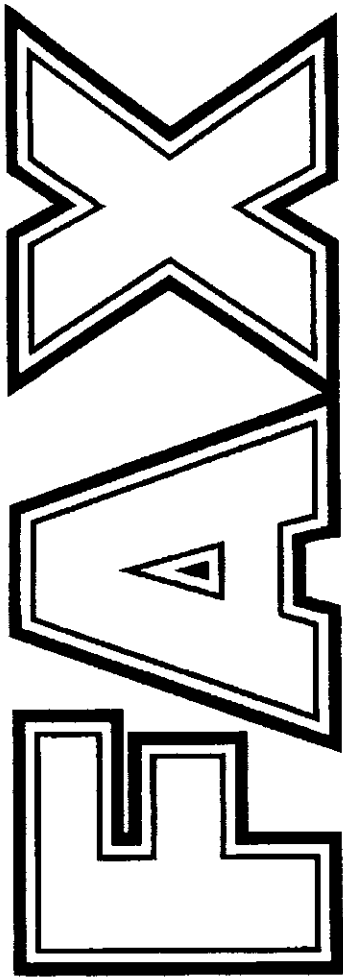
## **DOD FY 1999 APPROPRIATIONS CONFERENCE**

### **EXCEL STEM CELL PROJECT**

The conferees urge the Department of Defense to give strong consideration to the potential benefits, both military and civilian, offered by the EXCEL Stem Cell program during its evaluation process. The \$7,000,000 needed by the EXCEL program in FY 1999 would ready the technology for clinical trials and provide the nation with a new and aggressive treatment for individuals exposed to weapons of mass destruction (WMD). In addition, EXCEL is likely to benefit a third of the nearly 600,000 Americans who fall victim to cancer each year.

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**T R A N S M I T T A L**

To: Admiral Elmo Zumwalt  
Fax: (703) 528-5795

From: Rand H. Fishbein and Julie W. Fishbein  
Fishbein Associates, Inc.

Date: September 17, 1998

Pages: 6 including cover

**Fishbein Associates, Inc.**  
**7102 Plantation Lane**  
**Rockville, MD 20852-4421**

**Telephone: (301) 770-7987**  
**Fax: (301) 816-2441**

# Science Research Laboratory, Inc.

1530 NORTH KEY BOULEVARD  
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ARLINGTON, VA 22209  
FAX (703) 243-7139  
(703) 522-6390

September 21, 1998

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Admiral Elmo Zumwalt, Jr.  
Admiral Zumwalt & Consultants, Inc.  
1000 Wilson Blvd.  
Arlington, VA



Dear Admiral Zumwalt,

I spoke with Rand Fishbein this morning and he told me of his conversation with you.

First, I would very much like to thank you for your interest in this stem cell project and for your support. I very much appreciate the time you have spent with me over the past several months. I have some idea of how busy you must be in your many duties, both for the charitable organizations you serve and in service to your Country. Your enthusiasm for the project has helped me continue even when I was quite discouraged and when my other duties threatened to sidetrack me.

I will continue to interact with Dr. Howe and Captain Hartzman, and I will keep them apprised of our efforts, though I must admit that I am not hopeful at this point. I have done all that I can to persuade Captain Hartzman of the possible benefits of the proposed program. I believe that his reluctance is based on the fact that we do not now have the answers to all of the technical questions. For this reason, I contacted Dr. Parchment of the Karmanos Cancer Institute, and he joined our discussion on Wednesday and corroborated the possible benefits and furnished all of the supporting data for the project that he could. Key staff members at Karmanos also furnished a letter in support of the project.

I am persuaded that Captain Hartzman now understands fully the potential benefits of the project. I believe his current position is based on his reluctance to impose on a friend, in this case Congressman Young, for a project in which a possible outcome is failure. I very much understand his reluctance, since I have the very same inhibitions myself in my relationships with my friends.

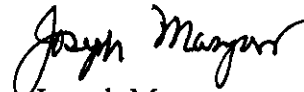
I believe that there is nothing anyone can now do or say, short of conducting the proposed research and getting a positive result, that will change Captain Hartzman's mind. Ironically, if we had such results, we would not need the Government to fund this

effort. There would be many companies in the private sector that would be more than happy to commit the necessary funds.

On the positive side, I am more persuaded than ever that my conjectures are correct, and that this new understanding will ultimately revolutionize how metastatic cancer is detected and treated. I will continue to seek funding for these new ideas from NIH and from whatever private sources might be available. My great interest in getting funding this year was to jumpstart the process in the hope of shortening the timeline to when these new treatments might be available to cancer patients.

Once again, I wish to thank you very much for your interest in this project and for your support. If you have any further ideas or comments, please feel free to contact me at (703) 522 6391.

Sincerely,



Joseph Mangano



**FISHBEIN  
ASSOCIATES, Inc.**

*Consultants to Government and Industry*

September 30, 1998

Admiral Elmo Zumwalt  
1000 Wilson Blvd., Suite 3105  
Arlington, VA 22209

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Dear Admiral Zumwalt:

On behalf of Science Research Laboratory (SRL) and the entire EXCEL Stem Cell project team, I want to extend to you our deepest thanks for your support during the conference on the FY 1999 Department of Defense Appropriations bill.

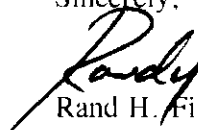
The Statement of Managers language adopted by the conferees provides important recognition for the EXCEL project at a time when its potential contribution to cancer treatment therapy could not be more urgent. Shortly, we will be applying to the Army for the necessary funds to move the project toward clinical trials. We are anxious to take you up on your offer to assist us in obtaining letters of recommendation that could be used to support our Army application.

As you know, what makes EXCEL so important is that it represents a fundamental breakthrough in our ability to isolate, concentrate and purify stem cells, one of the most basic biological elements of the human immune system. Its immediate use would be in the treatment of a range of malignancies, including breast, prostate, lung and colon cancer, the purification of bone marrow prior to transplantation and in the care of mass casualties arising from the use of weapons of mass destruction.

EXCEL is also an enabling technology that will provide researchers with a new and more powerful tool for exploring some of the earliest phases of cell development. There are indications flowing from EXCEL research that suggest that a cancer stem cell may exist, and that it may be responsible for "switching on" disease in well over 600,000 Americans each year. If confirmed, this discovery would alter our essential understanding of the morphology of disease and could aid in the economical development and testing of tens-of-thousands of new pharmaceutical agents.

Once again, it is with profound gratitude that we thank you for your support of EXCEL. We will contact you shortly to discuss the next phase in project strategy as well as the progress and prospects of this extraordinary technology.

Sincerely,

  
Rand H. Fishbein

# EXCEL STEM CELL PROJECT

## CONFERENCE REPORT (H. REPT. 105-746)

### TO ACCOMPANY H.R. 4103

### FY 1999 DOD APPROPRIATIONS BILL

105TH CONGRESS }  
2d Session } HOUSE OF REPRESENTATIVES { REPORT  
105-746

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RESEARCH, DEVELOPMENT, TEST AND EVALUATION, DEFENSE-WIDE

MAKING APPROPRIATIONS FOR THE DEPARTMENT OF DEFENSE FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1999, AND FOR OTHER PURPOSES

156

SEPTEMBER 25, 1998.—Ordered to be printed

Mr. YOUNG of Florida, from the committee of conference,  
submitted the following

#### CONFERENCE REPORT

[To accompany H.R. 4103]

CONFERENCE REPORT (H. REPT. 105-746)

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 4103) "making appropriations for the Department of Defense for the fiscal year ending September 30, 1999, and for other purposes," having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate, and agree to the same with an amendment, as follows:

In lieu of the matter stricken and inserted by said amendment, insert:

*That the following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the fiscal year ending September 30, 1999, for military functions administered by the Department of Defense, and for other purposes, namely:*

#### SUPPORT TECHNOLOGIES—APPLIED RESEARCH

The conferees urge the Department of Defense to give strong consideration to the potential benefits, both military and civilian offered by the EXCEL Stem Cell process. Providing funding for the EXCEL program in fiscal year 1999 would ready technology for clinical trials and provide the nation with a new and aggressive treatment for individuals exposed to weapons of mass destruction.



**E. R. ZUMWALT, JR.**  
ADMIRAL, U.S. NAVY (RET.)

December 7, 1998

Major General John S. Parker  
Commander  
U.S. Army Medical Research and Materiel Command  
584 Scott Street  
Fort Detrick, MD 21702-5012

Dear General Parker:

I am writing to bring your attention to some interesting and potentially important new insights that are being formulated at Science Research Laboratory (SRL), a small company near Boston which is applying the physical sciences to cancer research. They have postulated that there exist cancer stem cells that underlie metastatic cancer. They believe that these cells, because they would be primitive and quiescent, are the foci of metastasis and are essentially impervious to conventional chemotherapeutic agents, which are designed to work on rapidly growing and dividing cells. They also believe that they have developed some important new tools to isolate these cancer stem cells and prove that these cancer stem cells are indeed the carriers of the disease.

Preliminary experiments on a breast cancer cell line (MCF7) with these new tools have uncovered a small population of small, viable, and apparently quiescent cells that may be the postulated stem cell for this cell line. If these small cells are indeed breast cancer stem cells, then this discovery would have far ranging implications, impacting the early detection of metastatic cancer, the discovery of new and much more potent cancer therapies, including chemotherapies and gene therapies, and also impacting the complete purging of all cancer cells from bone marrow transplants, which are used in support of high dose chemotherapy.

Science Research Laboratory is teamed in these endeavors with researchers at the Massachusetts General Hospital and at the Karmanos Cancer Institute. At this time, the Science Research Laboratory has put together a plan for isolating these postulated cancer stem cells and then proving that these cells are indeed the most primitive cancer stem cells. These critical experiments would prepare the way for developing a new technique for the early detection of metastatic cancer by looking for these cells in small blood samples drawn from cancer patients following diagnosis. These experiments would also prepare the way for developing new chemotherapeutics and gene therapies by providing a means to test these new therapies in vitro on isolated cancer stem cells. Finally, these experiments would prepare the way for purging all

Major General John S. Parker  
December 7, 1998  
Page Two

cancer cells, including cancer stem cells, from bone marrow transplants used in support of high dose chemotherapy. These critical experiments can be completed within one year of the time when funding is received.

It is clear then that the discovery and isolation of cancer stem cells would have profound implications on the early detection and treatment of metastatic cancer. I have looked at these ideas myself, in some detail, and they appear to make sense from a purely logical point of view. I would very much encourage you to talk to Dr. Joseph Mangano, of SRL, about these ideas directly. He lives and works in Arlington, Virginia, and can be reached at (703) 522 6391. Dr. Mangano has talked to Colonel Rich and Colonel Raulin of your Congressionally Directed Medical Research Program about these ideas when they were in a more primitive state of development last summer.

I am hoping that you will evaluate these ideas and ultimately make them part of your Breast Cancer Research Program. I believe that given the broad implications of these ideas, it might be useful to evaluate them quickly in the laboratory and then, if warranted, in clinical trials to determine if they are sound.

Sincerely,



E. R. Zumwalt, Jr.  
Admiral, USN (Ret.)

1000 Wilson Boulevard, Suite 3105  
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Tel: (703) 527-5380  
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*Don George*

# Science Research Laboratory, Inc.

15 Ward Street  
Somerville, Massachusetts 02143

*File*

Telephone: 617-547-1122  
Facsimile: 617-547-4104

Science Research Laboratory, Inc. (SRL) is a technological research and development corporation which was founded in 1983 by Dr. Jonah Jacob, an internationally recognized expert in laser technology. The company's primary objective is to develop commercial products based upon research programs conducted for the United States government. SRL has performed such research for the Defense Advanced Research Projects Agency (DARPA), Ballistic Missile Defense Organization, Department of Energy, National Aeronautics and Space Administration (NASA), National Institutes of Health (NIH), and other government agencies.

SRL currently employs over 30 individuals, half of whom are scientists holding doctora degrees from some of the world's most distinguished universities. This talented group o researchers gives the company a broad technical base which has resulted in the development of a wide spectrum of technologies with applications in both the government and commercial sectors. These technologies include: electron beam curing composite materials, plasma x-ray generation for advanced microlithography, Dual-Energy Digital Subtraction Angiography, and new approaches to hematopoietic stem cell isolation.

SRL is committed to the commercialization of technology developed under government research programs. Through an exclusive licensing agreement, the company has supplie all-solid-state krypton-fluoride (KrF) laser driver technology to Cymer, Inc., the world' leading supplier of excimer lasers for sub-0.35-micron lithography. These drivers are now used with lithographic tools manufactured by Canon, Nikon, and Silicon Valley Group in the production of semiconductors. The technology has dramatically reduced t annual operating cost of KrF lasers used in optical lithography.

SRL is also working with SEMATECH, a consortium of leading semiconductor manufacturers, to provide technological improvements for the next generation of argon-fluoride (ArF) lasers to be used in sub-0.25 microlithography.

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| Robert Pierce              | Electrical Engineer           | 617-547-1122 x137 <a href="mailto:Robert.Pierce@SRL.com">Robert.Pierce@SRL.com</a>             |
| Thomas Pond                | Research Technician           | 617-547-1122 x404                                                                              |
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| Stephen Theophanis         | Geophysics                    | 617-547-1122 x138 <a href="mailto:Stephen.Theophanis@SRL.com">Stephen.Theophanis@SRL.com</a>   |
| Roger Thomas               | Research Technician           | 617-547-1122 x405                                                                              |
| Dan Weidman, Ph.D.         | Electron Beams & Pulsed Power | 617-547-1122 x201 <a href="mailto:weidman@srl.com">weidman@srl.com</a>                         |
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