

**FTS-NCI**

**October 27, 2005  
9:01 a.m. CDT**

Coordinator All participants are in a listen-only mode. Today's conference is being recorded; if you have any objections, you may disconnect at this time. Now, I'd like to turn the meeting over to Mr. Doug Ulman. Thank you, sir, you may begin.

D. Ulman Thank you. Good afternoon, everyone. My name is Doug Ulman and I'm the Chair of the NCI Director's Consumer Liaison Group. I want to welcome you this afternoon, to the first in a series of conference calls aimed at discussing the National Cancer Institute and allowing the advocacy community to learn more about the NCI's activities and initiatives.

Today, we're going to be discussing the 2015 challenge goal of eliminating the suffering and death due to cancer by 2015, the future of cancer research. For those of you who would like more information on future calls, please go to [www.la.cancer.gov](http://www.la.cancer.gov) where you can find information and register for those additional calls.

We are privileged today to have several speakers, Colonel Jim Williams, Dr. Andrew C. von Eschenbach, and I will be closing before Q&A with some additional comments about the role of the advocacy community in the future of cancer research. At the current time, I'm going to turn it over to my colleague and super cancer

advocate, Colonel Jim Williams, who is also a member of the DCLG, for comments that he is going to share with the group. Jim.

Col. J. Williams

Thank you, Doug. Good day, ladies, and gentlemen. I am a 14-year prostate cancer survivor, and I extend a special welcome to the cancer survivors and advocates on this call today. I hope my comments will stimulate thought and encourage you to participate in this and future calls in this NCI teleconference series.

How many times has someone come up to you and promoted some product they claimed to cure cancer? How often do you hear tales about someone who took something and was now “tumor free”? NCI recognizes that discoveries in cancer research are limited by the failure to apply new findings in a timely manner. However, there is a right way and a wrong way to accomplish our objective to eliminate cancer. In my opinion, evidence-based research is the only way to go.

My observations as a member of the NCI Director’s Consumer Liaison group has revealed to me that there is a priority shift from organ specific research to other advanced technologies and techniques, to include teen signs, personalized or individualized medicine, proteomics, naotechnology, a new world science that takes to a world 80,000 smaller than a ridge on your finger. Bio-infomatics improve imaging, bio-repositories and others.

What will be the role of cancer patient advocates in the years ahead as parties change from organ research to these new sciences? We in the cancer patient advocate community find ourselves at a crossroads. Do we continue to only pursue our disease-specific objectives? Do we understand that true collaboration among all of us will be the key, as NCI shifts away from site-specific research? Are we interested in only our own organ-specific disease or do we understand that the answer really lies within a much broader spectrum, for instance, molecular science.

Molecular counterization is much more than the change in emphasis, it's the basis on the knowledge of the process of cancer. The scientific community is being challenged to share information, specimens, and tissue that's noted in the creation of the National Biospecimen Network and the National Tissue Bank. We in the advocacy community also have a challenge to build uniform language and our strategic goals in test planning, which demonstrates a unified effort in the war against cancer.

Unfortunately, many decision-makers currently view the cancer advocate community as organ orientated, having a stovepipe mentality and very fragmented, providing conquer techniques that are often used successfully to keep us apart. The advocacy organizations would be more effective if they truly work in harmony. I might be wrong, however, I believe that true collaboration and partnership is the key to defeating cancer. It reminds me of our efforts in the Department of Defense with

military joint task forces, where each service brings different strength and a variety of resources to the table. However, duplication is minimized and the focus is on the enemy objection, not on who should receive the resources to complete the job.

I am pleased to note that in the restructuring of the clinical trial enterprise ... advocate involvement begins in the design phase and that the patient advocacy community is being asked to participate in all segments of the research process. These are exciting times in cancer research. However, we as advocates should one, begin to think out of the box. Two, figure out how we can truly speak with one voice to the decision makers and three, truly join forces with NCI to eliminate the burden of cancer by 2015. Thank you, Doug.

D. Ulman Thank you, Jim, very much. I think your experience as an advocate over the years is incredibly helpful, and I think your comments really resonate in terms where we need to go as an advocacy community if we want to reach the 2015 goal. At the current time, let me just remind everybody on the call that we will be doing a Q&A at the end of the prepared comments. At the current time, I'd like to turn it over to the NCI Director, Dr. Andrew von Eschenbach.

Dr. von Eschenbach Good afternoon. Let me begin by thanking all of you for taking time to join with us on this very important phone call, which is in very much a beginning. A beginning of a conversation that I certainly am looking forward to, between you – those of you

who are committed and concerned about our effort against cancer – and those of us at the National Cancer Institute who are committed to working with you towards an ultimate solution of the problem that we know is so devastating to so many of our friends and our family.

It's a conversation that I come to as not only the Director of the National Cancer Institute, but also a conversation that I come to as a physician and as a cancer survivor. From that perspective, it's so important that we have the opportunity to discuss and to share with you the National Cancer Institute's agenda and its effort in order for us to be able to make a difference in cancer.

It's important that we have this conversation because you have invested in us. As taxpayers, you have invested your dollars and your resources in the National Cancer Institute. Even more importantly, as an advocacy community, you've invested in us your hopes. Your hopes that we will be able to use the investment of the resources that have been given to us in an effort to make a difference.

That investment began in earnest in 1971. That investment of resources and the hope that the National Cancer Institute would be able to lead an effort to conquer cancer began in 1971 when we as a nation, targeted cancer. An effort to conquer cancer, a disease that we were aware then was causing a great deal of suffering and death that we're all aware of. It was a disease that we really knew very little about.

Our effort at the very outset was a commitment to cancer research. To be able to begin to understand cancer as the disease by targeting and focusing on cancer with regard to our research effort. I think over the years, it's important to realize that although cancer research was our focus, cancer research is not our end. Cancer research and the efforts of the National Cancer Institute are only a means to an end. The end is the importance of being able to affect the lives of those who are threatened by and those who are dealing with, cancer.

Research as a means is a critically important means. Without research, without our ability to understand cancer, we have very little chance of being able to accomplish or achieve that end. But we will never lose sight of the fact that it is the end that is most important. NCI has endeavored to frame that in terms of a commitment to – if you will – a dream with a timeline or goal. Our commitment is to be able to eliminate not cancer at this point, but to eliminate the outcome of the disease process of cancer. The outcome being the suffering and death that we see all around us.

As we are on this conference call today, not only are one out of every two men and one out of every three women at risk of being told in their lifetime that they have cancer, but the fact of the matter is that as we speak, one American every minute is suffering and dying as a result of this disease. The NCI is committed to eliminating

that suffering and death due to cancer by capitalizing on the effort that we have made in cancer research.

We have now begun to be able to understand cancer as a disease process. To understand that disease process at its very fundamental, molecular basis. We're beginning to understand the genes, the proteins, the molecules, and the interactions between cells that are responsible for this phenomenon we recognize as cancer. We're beginning to understand the interaction between the tumor and the person with the tumor, such that we can begin to understand what factors are determining and predicting the outcome of this disease process.

We believe that this knowledge is leading us to a period of time in which we have the opportunity to intervene in that process and preempt the initiation and the progression of cancer in an effort to be able to eliminate the outcome of cancer. The suffering and death we recognize and see all around us.

Cancer research is also being accelerated and facilitated by the fact that all around us we have an incredible explosion in advances that are occurring in technology. Technologies that are enabling us to understand genomics or the genetic basis for the development of cancer, our susceptibility to cancer, the procession of cancer. We're beginning to see technologies emerge in areas for example, that Colonel Williams alluded to in proteomics. Where by understanding proteins that are produced by

tumor cells, we're beginning to understand how we may be able to detect those proteins and define a signature for cancer. That even using one drop of blood or small amount of fluid, we can be able to detect the presence of proteins that would indicate the development and the presence of cancer very, very early on at a time where we can more safely and more easily eliminate it.

We're seeing opportunities in imaging. Where now we are dependent upon seeing a lump or the expression of a tumor once it is advanced, but be able to visualize the biochemistry and the biology of the disease process. Not only be able to see cancer at the molecular level rather than at the macroscopic level, but we're able to actually also see the impact of our treatments and our therapies in being able to alter or change the biology or the biochemistry of the tumor.

We're seeing the fact that we now understand the mechanisms that are responsible for a tumor's development and its progression. That understanding is opening the doors. That discovery is opening the door for the development of targeted interventions that are directed towards those mechanisms. We are daily seeing as we monitor the progress that's being made, the introduction of new drugs, new therapies, that are being able to target and directly impact on the tumor process. Gleevec for the treatment of leukemia was one of the early examples of a targeted therapy. There are many others that are also becoming and are available. Including for example, ... Herceptin for patients with breast cancer.

Every day we're seeing advances, but it is not simply enough to discover and develop new opportunities or new therapies. They must be delivered, and they must be delivered to all who are at risk or of need. In the actual delivery of these new interventions, we have the opportunity to learn even more about the human reality, the human biology, of cancer. Delivery is also becoming for us an extremely important opportunity for discovery. It will require a delivery system that not only provides access to and the opportunity for these interventions to be delivered, but allows for patients to actively participate in the process. Where their experience can be captured, the data can be recorded, assembled, and analyzed.

In that very experience, we will be able to learn more and ultimately do more about eliminating the outcome of cancer. The suffering and death due to the disease, and in the process, reduce the burden and the occurrences of cancer. Ultimately to be able to prevent more cancers from ever developing, to be able to detect and eliminate cancers much earlier in the course of the disease. To be able to control or modulate other cancers in a way that patients live with and do not die as a result of the disease.

We've made progress since 1971 in cancer research in terms of our understanding of cancer. We've moved from an era where the only way that I as a urologic oncologist could diagnose prostate cancer was based on what I could feel with the tip of my index finger. We've moved from an era where the only thing we knew about a

tumor is what we could observe by looking at the cells under a microscope. To now a time where we can actually work inside the cell and look at the genetic and molecular mechanisms that are driving that cell. Look at the genetic and molecular make up of the person with that cancer, and that has opened the doors to an entirely new reality, an entirely new set of opportunities.

It is the future that the NCI is committed to working together with you to explore and to implement. We're looking forward to being able to do this as a community in which all the parts and all the components are crossed. Discovery, development, and delivery must come together. Work and integrate together so that we can assure a nation and a world threatened by cancer that no one need suffer and die as a result. I'm going to turn it back over to Doug Ulman, and look forward to our opportunity for questions and answers.

D. Ulman

Great. Thank you, Dr. von Eschenbach. I'm going to take just a few minutes to talk briefly about what I see as the role for advocates in the community to propel us towards the future of cancer research and the 2015 goal. It's evident by the comments of Dr. von Eschenbach that the community is really crucial if we are to reach our collective horizon and this 2015 challenge goal.

Again, this is first in a series of teleconference calls aimed at providing another way for the community to interact with NCI. I feel strongly that the institute values the

voice of consumer advocates, and we need as a community of advocates, to provide a constructive voice, constructive ideas, and really create the dialog.

There are many ways to get involved from an advocate standpoint in the National Cancer Institute's efforts and initiatives. The DCLG has launched a Web site called Listens and Learns. There is the CARRA program. There of course is the DCLG itself. We will be taking nominations later this year for new members for that initiative. We are also in the preliminary stages of planning a summit for 2006.

The goal of the DCLG is to serve as a conduit to the cancer advocacy community, and we welcome your interaction and participation through all of the means that I just mentioned. As a community, we must truly come together to focus our energy on the new world of cancer research. The world that Dr. von Eschenbach just explained. That is the crosscutting issues that will ultimately get us closer to the 2015 goal.

These initiatives are the key to the future of cancer research, and we must put aside our specific disease sites and channel our energy on the larger issues that are plaguing the cancer research enterprise. If we collaborate and work with the research community in a constructive manner, we will catapult ourselves towards the 2015 goal. We will all witness a day when no one suffers and dies from this illness. As the Chair of the DCLG, I welcome your input. I encourage you to attend our

public meetings. I look forward to working with you to ensure that we don't miss this opportunity to transform the cancer advocacy community into a force that allows us to reach the 2015 goal.

Let me just briefly mention before we move to question and answer that we encourage everyone to join us for the remainder of the Understanding NCI series to learn more about the crosscutting issues in cancer research. Members of cancer advocacy organizations, survivors, family, and friends are encouraged to participate in each call to learn more about NCI's important cancer research programs and how advocates are involved. Participants will always have the opportunity to ask questions of the various panel members.

For more information you can go to the Web site for the Office of Liaison Activities, which is [www.la.cancer.gov](http://www.la.cancer.gov). Additionally, questions can be e-mailed in for a follow-up to the following e-mail address: [liaison@od.nci.nih.gov](mailto:liaison@od.nci.nih.gov). I'll repeat those again at the end of the call after the question and answer period.

At this time, we will open it up for questions for our panelists, Colonel Jim Williams, Dr. Andrew von Eschenbach, and myself. I believe the operator will provide instructions on how to ask a question.

- Coordinator Our first question comes from Ann Fonza. You may ask your question, and please state your affiliation.
- A. Fonza Thank you. I'm the President and founder of the Annie Appleseed Project. Our particular area of interest and expertise has been complementary alternative approaches. When NCI proposed reduction of pain and suffering, we were really excited because we see this as a real opportunity to look at the entire world of complementary approaches, which definitely have been shown to help reduce pain and therefore suffering.
- We'd like to see more resources put into that. Not just in the specialized of the Office of Complementary Approaches because that's a huge mandate, but more integrated. Can you speak to that?
- Dr. von Eschenbach Sure. I think one of the most important points to be made, as you were nice enough to comment on is that the goal is about both quantity of life as well as quality of life. Eliminating the suffering as well as the death associated with cancer is an important part of that. What we are increasingly becoming aware of is in looking at quantity and quality of life, and looking at opportunities from the perspective of understanding some of the fundamental molecular mechanisms that are associated with the process that we think about as cancer is that it really is a dynamic interaction between the tumor and the person with the tumor.

One of the important I think, areas of focus that we've seen coming historically from the area of complementary and alternative medicine has been the opportunities for a more holistic approach. The understanding of many of the factors associated with the person with the disease as well as the disease itself. We're very interested in many of the insights that have been able to be derived from components of what has traditionally been thought of as complementary alternative medicine. Including promoting programs that will look at those factors in terms of the role that nutritional interventions can have. The kinds of issues that are associated even with regard to interventions that are associated with relaxation, meditation, etc.

It's important that we do this in a rigorous and scientific way that not only determines and defines the impact that these interventions have on eliminating or reducing suffering as well as improving and enhancing survival and outcome. But that we also understand the mechanism, and that we understand what the molecular correlates are of these interventions, just as we must understand what the molecular correlates are of a new targeted drug.

We're committed to the inclusion of this important area in our portfolio. We're committed to the continuing scientific exploration of the important contributions that it can make. We're going to continue to do that in the context of our broader research portfolio.

- Coordinator Thank you. Our next question comes from Rick Wassermann. You may ask your question and please state your affiliation.
- R. Wassermann Yes, my name is Rick Wassermann. I'm with the National Patient Advocate Foundation. I was just wondering how we can as advocates, specifically best implement resources to unit and pool their resources? That's an open question for anyone to answer.
- D. Ulman This is Doug, I can take a first stab at that. I think that some of the things that we've been seeing coming out of different reports and coming out of the National Cancer Institute are really encouraging again, some of these crosscutting research initiatives. In doing so, are also encouraging things like team science and research angles of the future, which hopefully will allow people in the research field to work together.
- I also should mention things like the National Biospecimen Network as well as CAB, which are two initiatives that hopefully will provide platforms for researchers to share information, share data, and work closely together to expedite the development of the research enterprise. I don't know, Jim, if you want to comment on that? Or Dr. von Eschenbach, if you want to comment on that?

Dr. von Echenbach Yes, this is Andy von Eschenbach. I think there are a number of different dimensions to the question. Let me just focus on one of them. I alluded to earlier the importance of emerging technologies and how they were beginning to impact on this transition to a greater understanding of cancer. Particularly as we understand patient experiences. Last week for example, the results were released from the digital mammography trial. Which in the early diagnosis of breast cancer, the use of digital mammography as compare to film mammography showed across the entire population, they were equivalent and were of equal value. In fact, in a subset of patients – those who were younger, women who had dense breasts or were pre or perimenopausal, the digital mammography was actually superior.

One of the advantages and interesting implications of this study, which hasn't been really fully discussed, is not only is this a very important step forward in our ability to accurate diagnose breast cancer earlier and especially for this one group of patients in particular, but it puts all that information on a digital basis. The patient's information, the patient's data now is able to become a part of an electronic medical record infrastructure. It could conceivably enable us to electronically be able to assemble and assimilate all of the information that's coming from opportunities to detect breast cancer using digital technology, and create a database that we could extract knowledge from.

Patients willingness to participate, to contribute their data, their information, their medical records, in an appropriate, protected, confidential way. Patients as Doug alluded to, who would be willing in their experience to make available their tissue and their fluids for part of the advances that we need to make in our molecular understanding of cancer. Allows the patient to not only be the recipient of the benefits, but also one of the drivers of the progress that we could ultimately make.

A greater awareness of the community that can come from patient advocates to help others understand the importance of their participation – not just in clinical trials, but in clinical registry. Not just being involved in research to test new drugs, but the willingness to use their experience and the information that they have in our ability to create databases is a very important contribution to the future of cancer research.

Coordinator            Thank you. Our next question comes from Loren Pace. You may ask your question and please state your affiliation.

L. Pace                    Loren Pace, Breast Cancer Help Incorporation and founder of the Breast Cancer Mapping Project. This is a very exciting time for cancer patients to give them some hope and it's wonderful what the NCI is doing. However, my question is will you be using the geographic information system to find out where the concentration of breast cancer is? To hopefully help those people and to do some bio-monitoring to find out – of course you would need tissue banks and blood banks – to find out

where there's a concentration of certain kinds of cancer? Is it from some sort of chemical or the environment? Will there be studies being done on that and will the geographic information system be used? In my opinion, what we need is a national database with very important information about cancer.

Dr. von Eschenbach This is, like the other questions, an extremely important one and one that we are looking forward to in the future as an exciting opportunity. It begins with the point that you've made about how essential it is that we understand gene/environmental interaction. The problem of cancer is not only one of our inherent susceptibility, but it's also a fact in terms of what our exposures are and what various insults may be that precipitate and drive the genetic damage that gives rise to the cancer problem.

There are a number of opportunities that we've been engaged with. You alluded to one; we've had collaborative interactions with NIEHS in terms of being able to create an understanding of environmental carcinogens and gene/environmental interactions. We have a plan, which is another way of being able to look at the occurrences or the incidences of cancer in geographic areas across the United States with their particular types of cancers. Then also expanding that into the kind of programs that could be appropriately implemented in those geographic areas to deal with that particular cancer burden.

Then the ability to create mechanisms to survey and to provide surveillance for the emergence of cancers, where we then have the opportunity to correlate that with environmental and geographic factors that might be causation factors is an important one. The Long Island breast cancer study issues that are occurring now, and Marin County are just a couple of the examples of the important opportunities that we have in that regard.

L. Pace                      Thank you.

Coordinator                Thank you. Our next question comes from Sue Sumpter. You may ask your question and please state your affiliation.

S. Sumpter                 Hi, I'm Sue Sumpter. I'm a member of the DCLG and work for the leukemia and ...  
  
I want to thank you so much for doing this education series. I think it's a wonderful way to inform the cancer community and I want to say thank you first of all. My question refers to childhood cancer research and the poor number of clinical trials that there are for cancer research for children, especially the age group 15 to 25. I wondered if there was going to be any emphasis placed on that in the future?

D. Olman                    Thank you, Sue. This is Doug, and I'll take a first stab at that. Interestingly enough, the National Cancer Institute has just launched the initial phases of a progress review group to study the issue of young adult oncology, which is what you reference in

your question. For those who are unaware, this is an understudied and often neglected population. Generously I guess between 15 and 35 years of age. If you look at the relative five year survival data for this age group, the increases if any, over the last 20 years, have been minimal.

Realizing that and working closely with a number of organizations in the advocacy community – the NCI agreed to partner with the advocacy community to launch a progress review group. Which will take about 12 months, and hopefully then will lay out a series of recommendations based on the PRG that the community will really have to come together to implement. The implementation will not be left solely to the NCI, but rather the community at large.

I think from your standpoint and the standpoint of your question, it is clear that that is a topic of interest. It is a way that we can further reach towards the 2015 goal. We need to do a lot in terms of understanding not only the biological factors, but also the quality of life and survivorship issues that impact people in that young adult age range.

S. Sumpter Thank you.

Coordinator Thank you. Our next question comes from Polly Liss. You may ask your question and please state your affiliation.

P. Liss                   Hi, I'm Polly Liss with the ... national capital area of the National Breast Cancer Organization. I have two rather quick questions. One is will the 1-800-4CANCER service be able to provide to the consumer where to find the latest discoveries in relation to cancer? There are so many different outlets to look for this information the average person doesn't know where to look for it. If you happen to hit on the right page in the newspaper, you could have gotten the information that you mentioned a little while ago about the digital mammography. It would be nice if there was one place we go to tell us where to go.

The other question I had when you mentioned knowing that you can look inside the cell and you want to relate that with the genetic make up of the person. I was wondering also, does the personality of the person beyond the genetic make up contribute in any way to what happens with the cancer cell?

Dr. von Eschenbach   Let me take that in two parts. First of all, the 1-800-4CANCER is our cancer information service, and that is a very important portal for being able to direct patients, families, as well as healthcare professionals to all of the various assets that we have to specifically address questions, concerns or issues that they may raise. One very important more recent opportunity along those lines is number one, the ability to disseminate the information I alluded to earlier about the digital mammography trial and how people understand that.

Also, it was very important as cancer patients after Hurricane Katrina in those areas, were seeking or looking for advice and direction. This was an opportunity for us utilize the cancer information service in that 1-800 number. Particularly working with the American Society of Clinical Oncology to help patients and to help support even displaced oncologists. It's a comprehensive, very broad way of connecting patients with a particular need to the resources or the specific portal that they need to go to or have access to in order to be able to address that particular need.

It's also important to realize that [www.cancer.gov](http://www.cancer.gov) is another portal and another way of accessing information and being able to determine resources that are available and required. Of course, we have an important partnership with the American Cancer Society, and they have a call line service that's available 24 hours a day, seven days a week. They can provide important information or an important link and collaborator to help patients. They're also an important resource.

We've attempted independently, as many of you know, to create a publication that we issue every week called *Cancer Bulletin*. That's an opportunity to simply make everyone in the community aware of some of the things that are occurring at the NCI, some of the latest advances that have occurred. Areas that we are considering to be high priority programs that we're implementing, or even just simply insights

for example, in the director's update, to what we're thinking. What some of the important issues are that we believe need to be addressed.

We're trying in an open and transparent way, to provide as many portals as possible to the community to help them understand what the NCI agenda and programs are, what the resources are that are available to them and how we can guide them through the system and the problems. Anyone want to add to that question?

In regard to your second question regarding personality, I do not know the answer to that. I think that is a legitimate area of important investigation. We are continuously becoming more and more aware of – as I alluded to earlier – the need for a holistic approach to the cancer problem and to the person who is threatened or affected by cancer. What role emotion, what role mood, play in the entire process, what those correlates are that may perhaps have some expression in the endocrine or hormonal ... or the immunologic or immune responses, are areas of legitimate important investigation.

What are we viewing going forward in the future is the opportunity to really not only be aware that these things seem to and appear to be an important component as we observe the problem of cancer. To more importantly be able to delve into them in a way that we'll understand the mechanisms and the processes in terms of how they affect the ultimate outcome of cancer, and then what we can do about that in

terms of being able to get a more positive outcome as it relates to the cancer problem itself. These are areas yet to be explored, but areas of important opportunity.

P. Liss                      Thank you.

Coordinator                Thank you. Our next question comes from Judy Allen. You may ask your question and please state your affiliation.

J. Allen                      Hello, my name is Judy Allen, and I am a member of the UCSF ... Advocacy Core. I'm also the advocate member of the Breast Tissue Use Committee. I'm also a breast cancer survivor of ten years, and I just called the hospital where my surgery was done to see where my tumor was. I kind of suspected that after ten years their policy is to discard tumors. I told them please hold on to my tumor and I'd pick it up. I've sent an e-mail to our Breast Tissue Use Committee asking them to consider a program where we might be able to work with either the Cancer Registry or some program to see if we can't recover tissue that is expected to be discarded from hospitals that don't have a tissue bank. How we might go about getting retroactive consent from patients regarding their tissue?

At the same time, which I think is really important, is do an informational – maybe a national – informational program or campaign that basically educates people about tissue donation in the same sort of way – with a difference obviously – of organ

donation. Organ donation obviously is a method ... but tissue donations so that people understand what a valuable resource it is in discovering and curing and coming up with treatments for disease. Not only that, that if you do donate your tissue, that every effort would be made to maintain confidentiality as well as to let them know that they're not going to lose an extra scoop of tissue during their surgery in order to participate in tissue donation.

That's a very strong interest of mine. I think it's one that is not addressed as broadly as it should be because of the fact that so many resource organizations whether it's industrial or academic, are requesting tissues for this important research that's going on. Particularly with the new targeted research efforts. That the resources are limited, and I think that we have the opportunity to go and collect these tissue specimens from other hospitals. I'm wondering if there's any way that perhaps the NCI could get involved in this effort?

Dr. von Eschenbach Thank you for that question, and I'm going to follow it up with both an answer and a request, so I'll forewarn you. First of all, let me begin with the answer. This is going to be an exceedingly important area for us to address, and we have already begun the process in a number of important ways.

First of all, working through C-Change, which is formerly the National Dialog on Cancer. The NCI has spearheaded an effort to create a blueprint for a national bio

repository system. It's extremely important that we address this from the perspective of quality control and standards. The blueprint is a community-based collaborative effort that has brought all the components and parts and pieces to address the issue. How we can put a system in place that captures the resources that you were alluding to, but did it in a way that absolutely assured the quality that is critically important?

There are many issues with regard to these bio-repositories and the utilization of specimens. You've alluded to some of them having to do with the privacy issues and HIPAA regulations, informed consent, and many of the legal and ethical components. They are being addressed. The policies and the procedures that are necessary in order to do that appropriately and maintain confidentiality and privacy, etc., are all being addressed.

Also equally important is the realization that although tissue has been obtained and preserved, they were obtained and preserved not with the expectation that they would be used or needed for elegant genetic or molecular analysis years in the future. But would really be available for subsequent histologic examination or review under a microscope. Those involve two very, very dramatically different sets of conditions for how those tissues are preserved, how they're handled, and whether in fact they would be able to be effectively utilized. We have lots of tissue, but it's in various states, if you will, with regard to how it could be ultimately utilized for some of these molecular studies.

We've brought into the NCI, significant leadership in the form Dr. Carolyn Koffton to head up an effort to begin to move towards how we can look at all the bio repositories that are currently in place? How we could look at various specimens that have been maintained and kept for other purposes, and whether they could then be subsequently utilized for some of these elegant kinds of studies. We need help.

My request comes in the form of asking you and other advocates who want to help participate in being able to create this networking. If you would e-mail us at [liaison@od.nci.nih.gov](mailto:liaison@od.nci.nih.gov), your interest, your name, and your contact information. As we move forward in this important initiative and as we need to continue to network more broadly and more widely into the community. We need the participation and the support of interested and informed advocates such as you to help us to be able to create this kind of network, but do it in a way that is on an appropriate foundation of quality control and quality assurance. So that the materials are utilized appropriately and the information that is gleaned is valid and reliable and can be utilized in an effective way.

It's a work in progress, but we can't let these precious resources unnecessarily go to waste, and we're going to need your help both retrospectively as well as need your help prospectively as we go forward from here in terms of putting in place standards and networks. Not to create a central repository where we'll have all the material

captured and put in one place, but to have all of these distributed repositories adhering to a set of standards and quality control measures. So that your material will ultimately one day – when it’s needed – be in a condition and a state that we can then make sure that it would be able to be utilized appropriately and effectively.

J. Allen

Well, I thank you. I think the advocate component of this issue is extremely important because I think that there are trust issues with patients who don’t have as global of an understanding of research and patient confidentiality issues and consent issues as we would all like to have. I certainly will e-mail you and I’d really like to see a program in place to use these resources and have the patients understand how important their contributions are and what impact they would have on them personally, if any.

Dr. von Eschenbach

I agree. This is an important role for the Director’s Consumer Liaison Group as it serves as a conduit between the NCI and our programs and the broad advocacy community. I can assure you that there are people like Colonel Williams – who’s on the call and he may want to speak to this – who are both passionate as well as effective in being able to be certain that patient’s interests and perspectives are being not just represented, but taken into account and are a part of the planning and the implementation process. Colonel Williams, I don’t know if you want to speak to that role from the DCLG perspective or not, but I know you’ve been pretty vocal and adamant about the role of the patient and the advocate in this whole process.

Col. J. Williams      Yes, thank you, Dr. von Eschenbach. I would like to speak to that. I'm glad that question was brought up because it reminds me, what is the role of the patient advocate in the community? The tissue issue is one of those areas. I know I'm preaching to the choir here. However, I think we all appreciate that advocacy is very hard work. Many times there is little return on our investment of time and resources. Many times it's one on one with you on a patient or family member on one hand. Many times it's a health administrator or a politician on the other hand.

We have national programs that are very important, but the true patient advocate can have most influence in his community. Many decisions in medicine in this country are not based on the research that we're reaching for or those researched findings, they're based on advocacy. In those areas where advocacy has worked very, very hard, they've seen a lot of support for their specific calls. Where there hasn't been that advocacy, your party hasn't been there.

I encourage all of you who have listened on this call, when you're trying to figure out what role you can play. You can play a very important role as a catalyst within your community. Not only talking to patients as was mentioned before about the bioinformatics which is coming onboard, and their fear of the privacy issue, and how we need to overcome that barrier so the information is readily available when it's needed. The problem when we talk about clinical trials and being a guinea pig. Not

only is that phenomena in the minority community, but also those who get their service in an academic medical setting. Many times they're reluctant to participate and have more than "one person" look at them.

Remember we're still talking about the practice of medicine. I think the advocate plays a very, very important role and we're working very hard to be part of that medical team and more than just a recruiter or just as a spokesperson. As a patient we bring a lot of skills to the table. We're not brain dead just because we've been prostrate with prostate cancer. We have a dual role as I see it. We must work with our community members in trying to them bring them up to the level of awareness that we have come to because of our involvement in advocacy. We also have a job in trying to convince the health administrators and the health professionals that we truly can play an important role beginning in the development of trials and other protocols through the conclusion of finding a cure for cancer.

D. Ulman                      Great, thanks, Jim. I think we have time for one more question.

Coordinator                      Thank you. Our final question comes from Susanne Provo. You may ask your question and please state your affiliation.

S. Provo                              Hi, I'm with Young Survival Coalition and I actually have kind of a two-part thing. The first is that I think it is very important that we have patients involved in the

process of research. One thing I know right now is sitting in Congress is a bill to have some federal funding to allow patient navigators in various hospital programs. I know that that's for people with chronic diseases, of which cancer is considered one. I don't know how soon that will be implemented. I know it's supposed to be voted on in Congress very soon.

The other thing is that I am a young survivor and I am in research studies. I'm hoping that what they find with the research study that I'm in will help other people and I applaud the efforts that they're finally looking at young patients because so many of us are losing the battle. I'd like to know how the national government looks at how quickly the paradigm is going to shift as far as using complementary treatments?

I know a lot of patients, because I work with them, that are doing complementary things. They're looking at the alternative publications; they're doing a lot of research themselves. There are a lot of patients that are using the treatments because they feel they're getting good results. I know that the research basis, they would like it to be more scientific. You need to maybe speed up the pace because they're being used because people think that it's giving them a better quality of life. Could someone speak to those issues?

Dr. von Eschenbach Yes, this is Andy von Eschenbach. I'm going to be very quick. I really appreciate all the questions. I know there are many, many more and we're going to continue to take those electronically. Complementary approaches are extremely important that we factor those in to the traditional standard methods of intervention.

One thing that will help us a great deal in this regard is as we move toward an electronic medical record and the ability to have things more patient-centric and patients able to record and transmit and communicate information directly to us in the medical record. We would then not only know what treatments are being employed for example in the report of a clinical trial, but know all the other things that patients are doing and taking, whether it's vitamins or a particular nutritional supplement. That will give us the opportunity to really understand the implications.

We've seen more recently a clinical trial in which there was expected to be a very positive outcome from a particular intervention and it did not occur. It was hard to understand why that was the case. It was only when the investigators were able to go back and delve into the patients' history that they found out that the difference had to do with whether patients were or were not taking vitamin B-12. It's very important that we recognize the role that complementary medicine is playing. The fact that patients are engaging and accessing these interventions. We must be able to know about that and factor it in to this important equation.

With regard to patient navigators, we have reached out to HRSA, which is the agency that's been charged with the implementation of the patient navigator program. We have the benefit of having Dr. Harold Freeman, who is a special advisor to me, and has been the champion of the patient navigator program. As HRSA formulates its implementation strategy, now that the President has signed the Patient Navigator Act, we will be working with them to be certain that cancer is liaison into that. Hopefully we'll play a very important leadership role in the rollout of the patient navigator program through HRSA and the Department of Health & Human Services.

I'll very quickly give it back to Doug, and end by thank you all for your participation from my perspective.

D. Ulman

Let me just close by thanking our speakers, Colonel Jim Williams, and Dr. Andrew von Eschenbach. While we do know there are many of you on the call with questions yet to be answered, I would encourage you to use the e-mail address that we've given, [liaison@od.nci.nih.gov](mailto:liaison@od.nci.nih.gov). Additionally encourage people to visit the [www.la.cancer.gov](http://www.la.cancer.gov) Web site to learn more about this continuing teleconference series, Understanding NCI. The next call will take place on Wednesday, October 19<sup>th</sup> at 2:30 Eastern Standard time, and the title of that call is Why Statistics Matter For Advocates, Follow Up from the April 2005, CR Advocacy Conference.

Thank you again for everyone participating. We look forward to speaking with you, and again, we look forward to this only serving as the beginning of a long dialog, so that we can help reach the 2015 challenge goal. Thanks, and good afternoon.

Coordinator            Thank you. This concludes today's conference call. Thank you for your participation. You may disconnect at this time.