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THE FIGHT AGAINST CANCER: CHALLENGES, PROGRESS, AND PROMISE

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C O N T E N T S

THE FIGHT AGAINST CANCER: CHALLENGES, PROGRESS, AND PROMISE

WEDNESDAY, MAY 7, 2014

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:17 p.m., Room 562, Dirksen Senate Office Building, Hon. Bill Nelson, Chairman of the Committee, presiding.

Present: Senators Nelson, Whitehouse, Manchin, Warren, Collins and Ayotte.

OPENING STATEMENT OF SENATOR BILL NELSON, CHAIRMAN

The CHAIRMAN. Good afternoon. Today, the Committee will hear a progress report on a topic that touches all of us—the fight against cancer.

This Nation is blessed to have the greatest system of cancer care in the world. Patients are living longer and more productive lives thanks to advances in cancer research, and we are going to hear about that today, and that can be traced directly to the investments our country has made in the National Institutes of Health and the National Cancer Institute.

Dr. Francis Collins, the head of NIH, has told me that as a result of the sequester cuts a year ago that he had to stop dead in the tracks 700 medical research grants that were going out the door. This federal support has accelerated the pace of new discoveries and the development of better ways to prevent, detect, diagnose and treat cancer in all age groups.

While tremendous progress has been made—yet, we have a formidable opponent—a lot of folks are going to receive a cancer diagnosis this year and more than 585,000 Americans are going to die from the disease.

By the year 2030, cancer is projected to become a leading cause of death for Americans. Estimates are that we could see as many as 2.3 million people diagnosed with cancer annually, a 45 percent increase from today's total.

In the meantime, mortality rates remain extraordinarily high for certain cancers such as pancreatic, liver, lung, ovarian, ranging from 30 percent survival likelihood in five years to less than one percent, and yet, in other cancers, extraordinary progress has been made.

While we have this extraordinary progress in tripling the number of survivors in the last 40 years, the fact remains we know lit-

tle about the impact of cancer treatments on the body as it ages; thus, the subject of this Committee.

Though many have been cured by groundbreaking advances, there are still people across the country that are dependent on the next clinical trial, the next great research advance, the next NIH grant, that we hope the money is going to be there, to keep them alive just a little bit longer, and that is why it is imperative that we remain committed in this war, and one place to start is to renew our federal funding commitment to innovative research that is taking place at the universities, the oncology centers, the hospitals, much of it directed through NIH.

While we were able to restore a billion dollars in funding to NIH and the National Cancer Institute last January, unfortunately, their budgets remain far, far below what they had before this—I will be kind and say—unusual way of budgeting called sequestration.

I hope the Committee's discussion here is another step in a discussion of what we need to be doing and how much we need in order to be doing that.

I want to turn to my great partner in this Committee, Senator Collins.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, RANKING MEMBER

Senator COLLINS. Thank you very much, Mr. Chairman, and thank you for calling this very important hearing today to discuss the critical importance of funding cancer research and to highlight the progress that has led to significant improvements in the prevention, detection and treatment of this disease.

Our hearing will also examine the many challenges that cancer continues to pose for Americans of all ages. The American Cancer Society estimates that as many as 1.7 million new cancer cases will be diagnosed this year alone, including more than 9,200 in the State of Maine. While survival rates are improving, cancer continues to be the second-most common cause of death in our country, exceeded only by heart disease.

Cancer affects people of all ages; we all know that. However, it poses particular challenges for older Americans. The fact is that aging is the single greatest risk factor for developing cancer. More than 60 percent of cancers occur in people age 65 and older, and this percentage will only increase as the Baby Boom Generation ages.

Advances in treatment also mean that more people are surviving longer and now are aging with cancer. In fact, for many people, cancer has become more like a chronic disease.

Older cancer patients and their families often have different needs than those of younger patients. Health conditions that are common in older adults, such as heart disease, diabetes, high blood pressure, can affect cancer treatment and recovery as well as the type and severity of treatment side effects. Fatigue and weakness may be worse for older patients, and the chance of infection may be higher.

Social supports can also weaken with age as friends and relatives need assistance themselves or are no longer with us. It can be dif-

ficult for older cancer patients to find someone to help them at home or drive them to their daily treatments. This is particularly true in rural areas like my State of Maine, where cancer patients may have to travel long distances for treatment and transportation options are limited.

Even though cancer occurs most often in older adults, they often receive less frequent screening and fewer tests that can help determine the stage of cancer. Moreover, people with cancer over age 65 have been significantly underrepresented in cancer clinical trials even though they represent the majority of patients. Fortunately, I understand that this is beginning to change just as it is changing for women and minorities, two other underrepresented groups in clinical trials.

Mr. Chairman, we truly have an extraordinary panel of witnesses today, from two distinguished physicians to Valerie Harper, who was always one of my favorite television actresses as I was growing up, to Mary Dempsey, who is from the State of Maine, who you will find to be a ray of sunshine, Maine sunshine rather than Florida sunshine.

Mary is the Assistant Director and Co-Founder of the Patrick Dempsey Center for Cancer Hope and Healing in Lewiston, Maine. The Dempsey Center provides support, education and integrative medicine services to anyone affected by cancer, and it is a wonderful resource for Maine cancer patients and their families.

It was founded by Mary and her siblings—in fact, I was thinking we have gone from Rhoda to Dr. McDreamy today, among our witnesses, one of Mary's siblings—in honor of their mother, Amanda, who lost her 17-year battle with ovarian cancer this past March at age 79, and what a wonderful thing the Dempsey family has done in her memory.

Last, I want to give a very warm welcome to Chip Kennett, who I think would actually be more comfortable sitting behind us because he worked on my staff for two years, handling defense and homeland security issues. He is a bright and hardworking young professional, a devoted husband and a terrific dad. Unfortunately, he now knows firsthand the challenges of living with cancer.

I will leave it to Chip to tell his own story, but I just want him to know how much I admire his courage and that of his wife, Sheila, who is here today as well. They have fought his cancer with great courage, determination and grace.

Again, Mr. Chairman, I thank you so much for assembling such an extraordinary group of witnesses from whom I am sure we will learn a lot today.

The CHAIRMAN. Chip must have married up because his wife used to run Senator Rockefeller's office, and anybody who can do that has to be Merlin the Magician.

Mr. KENNETT. I did indeed, sir.

The CHAIRMAN. Now we have two spectacular Senators that have joined us, and I would like to call on them if they can resist the temptation of a Senator's disease, which is speaking way too long.

The great Senator from West Virginia.

Senator MANCHIN. Thank you, Mr. Chairman. I think I can.

The CHAIRMAN. Senator Manchin.

**OPENING STATEMENT OF SENATOR
JOE MANCHIN III, COMMITTEE MEMBER**

Senator MANCHIN. I think I can do that. I want to thank you again for this outstanding panel and thank all of you for coming here and sharing with us the hope that we all have.

I grew up in the little State of West Virginia. In those years, let's say prior to the 1970s, way back in the 50s and 60s, if you heard the word cancer, you thought it was over, you really did. There was little hope, and the achievements that we have had as a Nation since 1970 is unbelievable.

I still do not know of anybody in my little state where a family member or an extended family member has not been affected by cancer, so it really has touched all of us, and what you have done is extraordinary, and, doctor and for all of you in the research, and Valerie, sharing your stories, and all of you coming here—it is really something special.

We have the hope that we can continue, to continue to have the success we have had.

I think I was just reading here that we have been able to—since 1970, we have tripled, with nearly 14 million cancer survivors. We have come a long way—1 percent every year for the last two decades. Now that is pretty special, but we are a long way from finished, and we know that, and we know that we have to do our job, and it is going to take more research dollars and all of us being dedicated to this.

I just want to thank you, and I look forward to your testimony.

The CHAIRMAN. Senator Warren.

**OPENING STATEMENT OF SENATOR
ELIZABETH WARREN, COMMITTEE MEMBER**

Senator WARREN. Thank you very much, Mr. Chairman.

I want to start with an apology. We have got a Banking hearing running at the same time. I am going to be kind of back and forth, trying to manage both.

I want to thank the Chairman, and I want to thank the Ranking Member, for putting this together today. It is a powerfully important hearing that we have today.

We have all been touched by cancer, and so for you to come forward and give us hope is very important, but also give us guidance on the direction we go.

I am hoping to have many opportunities today to ask about, particularly about, our federal investments in research and the importance of those investments and how we make the most of what we can do and what we do know.

I also want to ask about palliative care when we have a chance, so that is what I would like to do, and I just would like to yield the rest of my time to go to our great panel here.

The CHAIRMAN. Thank you.

All of your written statements will be entered as a part of the record, and if you would just share with us for a few minutes.

First, we will hear from Dr. Harold Varmus, the Director of the National Cancer Institute out at NIH. He is a widely recognized expert and recipient of the Nobel Prize for his research, and then, Valerie Harper. Senator Collins has already told you about her and

not only as a very famous actress but now a very brave brain cancer survivor.

Dr. Thomas Sellers, the Director of the Moffitt Cancer Center and Research Institute co-located with the University of South Florida in Tampa, and Dr. Sellers is a researcher who will share some of his most exciting new advances and the barriers that remain to developing the science that we need for the most elusive cures.

Then, Mary Dempsey, the Co-Founder and Assistant Director of The Patrick Dempsey Center for Cancer Hope and Healing in Senator Collins's State of Maine. Ms. Dempsey is going to offer us a caregiver's perspective and share her work to provide for the social services needs for families during those troubling times, and then, as you have already heard, Chip Kennett, advocate and lung cancer survivor currently undergoing treatment.

Our two survivors here on the panel, with different kinds of cancer, will illustrate for the Committee about progress with new types of treatments, the complexity of the disease and where we might have fallen short of a cure, and so I want to particularly thank you two for sharing your personal stories with us.

We will start with you, Dr. Varmus. Thank you.

STATEMENT OF HAROLD E. VARMUS, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH

Dr. VARMUS. Chairman Nelson, thank you very much.

Senators Warren and Collins, thank you for your remarks.

This is a very opportune moment to discuss the relationship of cancer and aging. I will focus on that.

I appreciate your general remarks about cancer, which allows me to go directly to my topic.

The reason this is such an opportune moment is that life expectancy is increasing throughout the world. The number of people over 65 in our country especially, in the wake of the Baby Boom, is increasing, and we have made a lot of progress in cancer research, understanding the disease better and improving many aspects of diagnosis, treatment and prevention, lowering cancer death rates, the best single measure of our progress, by 1.5 percent on average per year over more than the last decade.

Let me show you a chart that reminds us about the demographics with respect to aging in particular. Most cancers are diagnosed in older age groups, and this chart shows the number of new cases grouped by age range in the U.S.

The number that are newly diagnosed with cancer is dramatically rising, from 1.7 million today to 2.5 million by 2040, despite the decrease in rate of incidents because the populations are increasing, and those increases are almost entirely confined to the three older age groups over 65.

We have not simply new cases but, as you point out, more survivors—people who had a cancer diagnosed at any time in the past regardless of their current conditions. Most of these are elderly. Most are living longer due to better treatment. We have gone, as you mentioned, Senator Nelson, from about three million in the

early 70s, and we expect to have 18 million survivors in this country by 2020.

I have three goals today, which will summarize some of my written testimony:

First, to mention something about the biological relationship of cancer to aging that underlies these epidemiological facts on the chart.

Second, I want to mention a few ways to improve the control of cancer through prevention and screening and treatment, especially among the elderly, and, third, I want to say something about how we plan to expand our knowledge so we can improve cancer care in the future.

Throughout this discussion, you must remember the vulnerabilities of older individuals. Namely, they have coexisting medical conditions very commonly; we call these comorbidities, but those comorbidities can shorten life expectancy independently of the cancer and can complicate the delivery of cancer care.

Why is cancer so common in older people? We do not know all the answers here, but overall, we know that cancers, which are very different in character, are all caused by accumulated changes in a cell's genome, mostly mutations. Since these accumulate with age, the incidence of cancer also, in general, increases as we age, but the relationship of cancer to age is not simple, and not all cancer types show an increased incidence with advanced age. For example, some cancers, like a cancer of the eye, retinobalstoma, some leukemias, some lymphomas, some brain and bone cancers are largely confined to children, adolescents and young adults. Even cancers that are common at advanced ages can occur in young people, and we are going to hear about that today, but we can learn from these exceptions to the general rule.

How about prevention—obviously, our greatest tool if we can exercise it properly? In general, cancer prevention has four basic strategies:

Avoiding cancer-causing agents or conditions like tobacco, obesity, infection with certain viruses.

Secondly, assessment of our own individual and inherited risk of cancer.

Third, the use of screening procedures, and, fourth, the use of some common drugs, like aspirin, that can reduce the incidence of certain cancers.

Let me mention three examples that are relevant to older populations.

We all know that tobacco, especially cigarette smoking, is the major avoidable risk factor.

Aging is not. It is a good risk factor. It is not avoidable.

That is true for many cancers but especially lung cancers.

Nevertheless, the health benefits of stopping tobacco use in middle age are underappreciated, and we do not know enough about the benefits of stopping in later ages.

Second, screening tests. Screening tests are controversial because we have arguments, legitimate arguments, about the cost-benefit ratios and about the ages at which screening should begin and stop. We know that some tests are not routinely recommended for people over a certain age because there are harms as well as ad-

vantages to these tests, because overall life expectancy increases as we age and, therefore, the benefits diminish and, thirdly, because certain cancers are less frequently diagnosed at older ages. We need to pay attention to those limits and communicate them successfully to older people.

Third, let me say a word about aspirin. We have great evidence that aspirin can reduce the incidence and mortality of quite a few cancer types including gastrointestinal and lung cancers. However, adoption of long-term chemoprevention is not usually—is not well accepted, especially in older individuals, because of gastrointestinal bleeding.

The NCI is currently collaborating with the Institute of Aging, that you hear from frequently, on a five-year study in hopes of providing information that can better guide the use of aspirin in elderly folks for chemoprevention.

Something about treatment. Historically, we have used less aggressive therapies in older patients, but that approach has been changing for several reasons.

First, we know it is important to distinguish between physiological age, a person's function, and their chronological years, the years they have been alive, and evidence suggests that healthy but chronologically old patients can withstand such therapies.

Secondly, they can benefit from them, and, third, there are improved methods to control the symptoms, like pain, nausea, immunosuppression, a suppression of the bone marrow, that often accompany cancers or their treatments.

Finally, we can recognize that both improvements in traditional therapies like surgery and radiotherapy, and the advent of newer therapies, targeted therapies and immunotherapies, are likely to produce fewer side effects, including, and perhaps especially, in older populations, so it is important to ensure if we are going to use all these therapies well that such patients are included in clinical trials, but now about two-thirds of patients in clinical trials are younger than 65 even though more than half of cancers are diagnosed in patients over 65.

There are reasons for that—comorbidities, traveling, prejudice against inclusion of the very old in trials—and these require further examination.

Finally, a word about what remains to be learned. I have already mentioned a number of things that the NCI is doing. We are also supporting work on fundamental aspects of aging and its relations to cancer to understand this relationship between aging and cancer.

For example, we have an initiative called the Provocative Questions program that has called for applications to try to study how the life span relates to cancer incidence in animals, where it varies widely, how biological mechanisms might influence susceptibility to cancer risk factors and what aspects of aging other than mutations might not only promote but also protect against cancers.

You hear frequently in this Committee about Alzheimer's and Parkinson's, and there is an intriguing observation that patients with these diseases seem to have a lower incidence of cancer, and we are trying to attract applications through our Provocative Questions initiative to answer those.

I will be happy to answer any questions you might have, and thank you for your indulgence in allowing me to go to six and a half minutes.

The CHAIRMAN. Well, thank you, Dr. Varmus.

Any Nobel laureate is entitled to go as long as he wants.

Dr. VARMUS. I have many friends I will communicate that to. Thank you.

The CHAIRMAN. Tell that to Dr. Collin.

Dr. VARMUS. She is not a Nobel laureate yet.

The CHAIRMAN. Ms. Harper.

STATEMENT OF VALERIE HARPER, ACTRESS AND CANCER SURVIVOR

Ms. HARPER. Oh, it did not stay on. Oh, anyway, good afternoon. I should learn to use the mic.

My name is Valerie Harper. Thank you for the lovely introduction.

I am pleased to be joined by my husband, Tony Cacciotti, and we are both very honored to be here.

I am a lung cancer survivor, and it was widely reported in the press that I had brain cancer.

I guess I am on the cusp. It is occurring in my brain, so you are correct, Chairman.

My neurological oncologist, Dr. Jeremy Rudnik, said, you know, Val, if it is in the lining of the brain, I claim it as my own, but what it is, is lung cancer. It is lung cancer, but it took them a month or more to ascertain that so I could be treated with one of the new kind of markers and genetical approach that the good doctor was speaking on.

Thank you, distinguished members of the panel for having me and letting me share my story.

I am really passionate about this not just because I have it but because of the enormous amount I learned about lung cancer that I did not know—the 15 percent survival rate against other cancers, where it is 88 percent survival rate, or with prostate it is in the 90s. I thought, oh, my goodness, my chances are not great.

Five years ago, March 2009, I needed surgery on my left wrist to repair an injury. I underwent the required pre-surgery chest x-ray, which shockingly revealed something that was in the top of my right lung that should not be there. It was a shock because I had experienced no symptoms whatsoever. None.

The wrist surgery was put on hold, and the tumor in my lung was diagnosed as stage two cancerous. I had no idea it was there.

Thankfully, my surgeon at Cedars Sinai, Dr. Robert McKenna, in 1992 had pioneered a truly brilliant minimally invasive lung surgery procedure. Video-assisted thoracic surgery—thank you, Doc—is akin to arthroscopic knee surgery but for the lung. It was an amazing advance for the patient, quick recovery and less pain. The whole thing was so much advanced.

A lot of areas do not even know about it. My doctor has done over 4,000 of these, and I was lucky to have that.

Every six months since that surgery in 2009, my lungs have been scanned for any sign of recurrence. My lungs have been free of lung cancer, surgically cured of lung cancer, for four years.

Then January 2013, there it came up again in a new form—leptomeningeal carcinomatosis, known as lepto, a rare and incurable cancer that occurs in the meninges. That is the membrane that surrounds the brain and the spine, and it is that space in which the fluid, the spinal fluid, exists. It protects us. It also keeps out bacteria, infection and chemotherapy, so we had to do some plain and fancy trying. It took a month of testing to conclude that my lung cancer had returned, not to my lung but to this area, and, although the original prognosis was terrible—excuse me.

By the way, I have laryngitis. This has nothing to do with cancer. Not enough sleep, okay.

The prognosis was truly dreadful, as I said; that is, it was an incurable, terminal disease with perhaps three to six months to live, but my spectacular oncology team, Doctor Ronald Natale and Dr. Rudnik, plus newly researched treatments, have extended my time on the planet.

My husband, Tony, makes sure I take my prescribed medications religiously, exercise, eat consciously, do not give up. I have regular brain scans and whole body testing twice a year to see if it is moving around.

I also take traditional Chinese medicine tea, TCM, which seems to help with the meridians, I am told. I have had acupuncture regularly.

I engage in visualization, which is actually an actor's tool kit, visualizing myself kicking out the cancer or making up scenarios. Some of them are funny.

I talk to them and say, you guys, if you do not go crazy, we can coexist, but you are killing the host, so, you know, I will accept you as my own, but let's be real, so I do all kinds of stuff.

I replace the fear of death with the joy and gratitude for each moment I do have, which these wonderful doctors and procedures have accorded me with.

I was struck by what you said because my doctors went after it aggressively with an oral medication.

Today, I am a year and four months past my expiration date due to these interventions, and I am really grateful for it.

The question I would ask myself is, why did I get lung cancer? What would have happened to me if it was not discovered accidentally?

Today, we can really confront the facts for a moment. You guys, with all you do for us in so many areas, are very versed on this, and I am thrilled that I am repeating what you have already said.

Lung cancer is the number one cancer killer in the United States among both women and men, and women have been on the rise as cancer patients-victims.

More than two-thirds of all lung cancers occur among never-smokers—here is one—or former smokers. As my doctor, McKenna, said, Valerie, I have so many patients who did the right thing and stopped smoking years ago, and yet, they are hit with this.

Lung cancer we have to face although absolutely no one should smoke. That is my opinion. I am a nonsmoker, but lung cancer can also be caused by secondhand smoke, air pollution, the environment and radon—a colorless, tasteless, odorless gas, and genetics, we are finding play an enormous role in developing lung cancer.

While I never smoked, I was exposed to secondhand smoke, as all of us have been, for decades.

My mother also developed lung cancer. She died of it. She, too, never smoked, so here were two risk factors—secondhand smoke exposure and possibly my genetics.

In my capacity as a lung cancer survivor, I have gotten involved with the American Lung Association. They advocate for increased federal funding for the National Institutes of Health, including the National Cancer Institute.

While I will not pretend to understand the federal budget, I do know research dollars equal lives. There have been recent amazing, truly exciting advancements, as you heard and will continue to hear, in fighting lung cancer over the last few years.

Tumors can now be tested, as in my case, for genetic markers that then they can hone in and say, what is the best drug for this; let's do that, and that certainly extended my life.

Landmark research conducted by the National Cancer Institute in this last decade has led to the U.S. Preventive Services Task Force awarding a B grade for screening for people with lung cancer if they meet the definition of high risk. Research is desperately needed for early detection.

I had not had a lung x-ray and would not have had one if I did not have my wrist problem, so people like me who are not at high risk for developing lung cancer, except for the age—I will be 75 in August, and I plan to make that birthday.

I do thank God that I broke my wrist and needed surgery. However, luck is not an appropriate method for early detection, so funding that will support means of early detection is absolutely imperative—and research on new treatment options that are just sitting out there. We are not sure about them, but they are so promising, and that is needed to detect stages of lung cancer three and four.

Chemotherapy is the first-line treatment for many lung cancer patients despite its difficult side effects.

For 20 percent of lung cancer patients with a known genetic marker, personalized treatments like I received are available—less toxic, more effective against specific tumors, but more work is needed on these biomarkers and targeted therapies.

Just because he talked about the aggressive approach, it has worked in my case. I really have had minimal side effects, and since they were, my doctors said, Valerie, you can take it; let's give you more; let's have you take it every five days, and we were—it was a work in progress, which worked out for me.

How can these investments in life-saving research occur when, excuse me, all we hear from Washington is about cutting spending?

We must stop thinking of spending—and I know you guys cannot; you have to—and gals. Do not think of it as spent.

Think of it as investing. Investing in the answers. Investing in all these magnificent saints who are doing the research, who are doing—the clinicians who are working with patients.

I just thank you.

I think I have run over—oh, only five seconds. That is good.

Thank you again for this wonderful opportunity, the pleasure to see you guys in person, to thank you for all you do and all you face.

I do not know how you get up every morning and go in and fight the good fight, but I thank you for it.

Please, let's get those dollars rolling toward real advancement, not just against lung cancer but all cancer.

Thank you.

The CHAIRMAN. Thank you, Ms. Harper.

You know, you do not have to convince the Senators here.

Ms. HARPER. I see that.

The CHAIRMAN. I wish we could have you talking to some of our colleagues.

Ms. HARPER. You can.

The CHAIRMAN. All right.

Ms. HARPER. I am up for it. Take me in.

The CHAIRMAN. Dr. Varmus, I think you have got a new helper when you go in front of the Appropriations Committee.

Dr. VARMUS. We very much welcome her continued existence.

The CHAIRMAN. All right.

Ms. HARPER. I cannot say anything too wrong. It was not too bad.

Dr. VARMUS. It was great.

Ms. HARPER. Okay. Good.

The CHAIRMAN. All right, Dr. Sellers, tell us about some of your groundbreaking research.

STATEMENT OF THOMAS SELLERS, PH.D., M.P.H., DIRECTOR, H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE

Dr. SELLERS. Chairman Nelson, Ranking Member Collins and members of the Committee, good afternoon. I am pleased to speak as the Director of the Moffitt Cancer Center in Tampa, Florida and as a recent member of the board of directors of the American Association for Cancer Research.

I do not have a Nobel Prize, and I am not a famous actor, so I will try to stick closer to the five minutes.

The State of Florida has nearly 20 million residents, and almost one in five is older than 65 years. That is the highest percentage in the country and why some sarcastically refer to Florida as heaven's waiting room. By 2030, one in four will be over 65.

Although Florida is the fourth most populous state, it is second in the Nation in overall cancer incidence and mortality. Within the state, cancer is already the leading cause of death. Thus, aging and cancer is an especially significant concern for the state I live in.

Since its inception in 1986, the Moffitt Cancer Center has had a single mission—to contribute to the prevention and cure of cancer. Our hospital and outpatient clinics treat more than 50,000 patients per year from all 50 states and 78 countries from around the world.

In addition to taking care of cancer patients, we have a thriving research enterprise, representing about 20 percent of the 4,300 member workforce. We are supported by more than $50 million in research grants and contracts, primarily from the National Cancer Institute.

Moffitt is the only NCI-designated comprehensive cancer center base in Florida.

From the window of my office, I see dozens of cars lining up each day, filled with cancer patients, their family members and friends. They are coming to us for one reason—hope. Their hope often lies in the opportunity to participate in one of the 400 clinical trials that we have open at our institution.

We have a Senior Adult Oncology Program. It is the first of its kind in the Nation. Based on rigorous and empirical clinical research, our multidisciplinary team of experts has made great strides in learning how to tailor cancer treatments to each patient based on their biological or physiological age and not their chronological age.

This is an exciting and promising time in science and cancer research, and that research is having an impact. The cancer death has declined by more than one percent each year for the past two decades, resulting in over a million lives saved. The number of Americans living with, through or beyond a cancer diagnosis has almost tripled since the 1970s.

According to the most recent AACR Cancer Progress Report, 13 new drugs to treat a variety of cancers, six new uses for previously approved cancer drugs and three new imaging technologies have been approved in just the past 18 months. Moreover, there are now 41 FDA-approved therapies that target specific molecules involved in cancer—like your good news there.

Ms. HARPER. Yes.

Dr. SELLERS. That is compared with seventeen, five years ago and just five, ten years ago.

These results are directly related to the past investments our country has made in the NIH and the NCI.

At a time of unlimited potential for further progress, the enthusiasm of the scientific community is bridled with sobering realization that the resources needed are simply not available because of demoralizing decreases in funding.

Despite the additional funds provided in the current fiscal year, the NIH and NCI budgets remain below fiscal year 2012 levels and below levels prior to sequestration. In fact, the NIH has lost more than 22 percent of its budget after inflation over the past decade.

These cuts not only have a negative impact on the pace of biomedical research productivity but also on future generations of scientific investigators. The competition for research grants is so fierce that it is driving many new investigators out of the field before they even get in the game.

I used to think when I was younger that 55 was ancient. I am realizing, now that I am 55, that is not so old, but I look around, and I wonder, who is going to be there to carry the torch and continue in the future the fight for biomedical research?

There has been progress against cancer. The opportunity to make a significant impact based on recent discoveries—sequencing of the genome we have heard about—and amazing technological advances at our fingertips.

The need is great. More than 1.7 million Americans are expected to receive a cancer diagnosis this year, and one person will lose their battle to cancer every minute of every day.

Cancer is clearly not only a costly disease in terms of lives lost but also costs our country more than $215 billion in direct and indirect costs.

The Federal Government has an irreplaceable role in supporting medical research. No other public, corporate or charitable entity is willing or able to provide the broad and sustained investment in research necessary to enable success. This will require an unwavering and bipartisan commitment from Congress and the Administration to invest in our country's remarkably productive medical research enterprise.

With robust support, research can help us to accomplish the ultimate goal once articulated by the late Dr. Ernst Wynder—to help people die young at an old age.

Thank you, and I look forward to answering any of your questions.

The CHAIRMAN. Thank you, Dr. Sellers.

I want to offer to you all, you brave souls that are standing, there are plenty of benches right here, and so I hope you will come up and avail yourselves of please making yourself comfortable. Come on. Come on.

Well, at least the ladies. Ladies, come up here. This is my authority as Chairman.

Thank you, Dr. Sellers.

Ms. Dempsey.

STATEMENT OF MARY DEMPSEY, ASSISTANT DIRECTOR AND CO-FOUNDER, THE PATRICK DEMPSEY CENTER FOR CANCER HOPE AND HEALING

Ms. DEMPSEY. Chairman Nelson, Senator Collins and the members of the Committee, thank you for inviting me to speak today.

My name is Mary Dempsey, and I am the Assistant Director and Co-Founder of the Patrick Dempsey Center for Cancer Hope and Healing. We offer free support and education available to anybody impacted by cancer.

My mother, Amanda Dempsey, was diagnosed with ovarian granulose tumor cell cancer on August 19, 1997. Over a course of 17 years, my mother had a total of 12 recurrences. As my family navigated the first two occurrences, we realized the necessity for emotional and community support that patients and families need when going through this unknown experience.

My brother, Patrick—McDreamy—assisted in the partnership of Central Maine Medical Center, where we joined an experienced oncology social worker to develop the concept for a local cancer support center with a caring warmth and provided opportunities for healing that would be accessible to anybody impacted by cancer.

I understand firsthand the cancer diagnosis feels like a death sentence.

There have been tremendous advances in the field of oncology that now allow more people to live with the disease as a chronic illness.

My mom lived this experience, and I shared it with her as her primary caregiver. In this role, I experienced firsthand the impact of cancer that it had on every part of my life as well as my mom's and my family's. For me, it really became a full-time job, navi-

gating resources, understanding the medical world and coping with the profound changes in our lives.

While physicians and other oncology professionals provide great medical care to treat the disease, cancer patients and their families need additional support to treat the person and those who surround them. Cancer affects the whole person and the whole family.

At the Dempsey Center, we understand that the resources that are strained at first when things are often sacrificed is the emotional care needed to endure ourselves through these tough times. As a result, the Dempsey Center offers an array of services including professional cancer support, education, integrative medicine and services for all ages, free of charge, regardless of where the patient receives their medical treatment.

Much like other cancer treatment centers, we provide many opportunities for people to give back to such great comfort items. Donating time and skill, they help the Dempsey Center operate and, of course, volunteering at our annual Dempsey Challenge. These volunteers can certainly be patients or family members or just others wanting to give back to make a difference.

Patrick helps sustain the center financially through not only his own generous contributions but his vision of the Dempsey Challenge, our largest annual fundraising event. The challenge is an event, not a race, where patients and families and communities from all around the world come together to support a cause which is common in many homes.

At this event which, by the way, is September 27th and 28th this year, it has more depth than it may appear, just like the Dempsey Center. It is a community celebration, more importantly, a recognition that we are all in this together.

Every year since 2009, my mother has led the Amgen Breakaway from Cancer Survivor Walk, alongside with our family and many other cancer survivors, who came together to take their journey one step at a time.

My mom, Amanda, passed away this year. She will be there in spirit like so many others that have come before her and so many others that will come after her, and we will continue to work towards our mission of raising awareness, encouraging hope and offering healing through our collective presence.

In closing, mom passed away on March 24th of this year. She did not lose the battle. She defied all odds and lived each day to the best of her ability. After all, this is what living with cancer is all about—not letting a disease prevent you from life; she is beating up cancer.

The mission of the center will forever be intact through her legacy and our commitment to help everyone impacted by cancer through their journey as gently as possible. We will continue to be the beacon of light in the thickness of the fog.

Thank you for having me.

The CHAIRMAN. Thank you, Ms. Dempsey.

Mr. Kennett.

STATEMENT OF CHIP KENNETT,
ADVOCATE AND CANCER SURVIVOR

Mr. KENNETT. Chairman Nelson, Ranking Member Collins and members of the Committee and staff, I want to thank you for holding this hearing on a subject that has, excuse me, touched the lives of everyone in this room, but, as I have learned over the past 18 months, you do not have a complete understanding of everything that is involved in a cancer diagnosis until you receive one.

I am grateful the Committee is taking the time to explore this issue, and I hope I am able to add value to the Committee's efforts.

Senator Collins, thank you for that very kind introduction. I did not expect to be testifying before the Senate at any time and wish it was for another reason, but at least I am not under subpoena.

The Committee has asked me to testify about my personal experience, so I will primarily be focusing on lung cancer, but I strongly support the funding for, and the eradication of, every single type of cancer.

My journey to testifying here today began in the fall of 2012. I was a 31-year-old father of a wonderful two-year-old boy named Joe, and my wife Sheila, who is here with me today, was 35 weeks pregnant with our baby girl, Crosby.

I was, by all accounts, healthy. I just had a nagging blurry spot in my right eye that showed up and would not go away.

I scheduled an appointment with my eye doctor who thought I had a detached retina. After seeing several eye specialists, I was told I potentially had melanoma of the eye, but it was recommended that I schedule an MRI and PET scan through my general practitioner.

That series of events led my wife and me back to the same doctor's office at which a few months earlier I had passed my annual physical with flying colors. We were told that the results of the PET scan were all lit up.

I had cancer "everywhere." It was in both of my lungs, my liver, my lymph nodes and my bones and, plus, my right eye and had subsequently traveled to my brain.

A week later a biopsy revealed I had non-small cell lung cancer. In just three and a half weeks, I went from seeing a blurry spot to being told I had a year, maybe two, to live.

Further genetic testing revealed I had a genetic cell mutation affecting less than five percent of adenocarcinoma patients, called ALK translocation. It is all relative these days, but we were ecstatic with this news actually because we knew there was an FDA-approved targeted smart drug that specifically treated this mutation.

Despite living through it, it is still difficult for me to put into words what that experience was like. It is not because it is emotional to recall those first few weeks, but there are no words to describe what it feels like to be told you have an incurable disease that will kill you.

I hope and pray no one within the sound of my voice has to experience what I am failing to describe, but unfortunately, the odds are many will.

One in every fourteen people receive a lung cancer diagnosis, and due to the lack of a reliable form of early detection, lung cancer is

the most lethal form of cancer. It kills more people each year than breast, colorectal, pancreatic and prostate cancers combined.

According to the NCI, approximately 160,000 people will lose their lives to lung cancer this year. That is the equivalent of a jumbo jet falling out of the sky every single day.

The five-year survival rate, which has already been touched upon, is about 15 or 16 percent.

For stage four patients, like me, the chances I will live more than five years is only one percent. That means I have a one percent chance of watching my kids grow up or growing old with my amazing wife.

Lung cancer kills almost twice as many women as breast cancer and almost three times as many men as prostate cancer, yet the funding lung cancer receives pales in comparison due primarily to the stigma that lung cancer is self-induced as a result of smoking. I had never smoked, and the stigma needs to end.

I have included a number of statistics in my testimony today, but I do not consider myself to be one; I never have, but stats are driven by facts, and the fact is more funding is needed for lung cancer research.

The bottom line is research saves lives. I am a living example of that. The drugs that have kept me alive for the past 18 months were not available just seven years ago.

The first drug I was on, Xalkori, is a smart oral chemo, which specifically targets the ALK translocation. Within a week of being on Xalkori, I regained my energy, my vision was almost clear, I was back to work and, most importantly, was present at the birth of my daughter. Unfortunately, after two months, the efficacy of the drug played out just as dramatically.

I was soon enrolled in a clinical trial in Philadelphia for another oral chemotherapy, a second generation ALK inhibitor, LDK378. The average response to LDK is seven and a half months, which is approximately how long I was on the trial before I started having major complications and progression of disease. However, during those seven and a half months, I watched my son turn four and my daughter turn one and my wife and I spent a week driving the Pacific Coast Highway, which is something we always wanted to do.

LDK, now known as Zykadia, is the same drug that received the FDA's Breakthrough Therapy Designation last week.

Unfortunately, earlier this year, the progression of disease was significant enough that my oncologist moved me to nontargeted intravenous chemotherapy. After two rounds of that chemo, scans revealed further progression of disease, so eight weeks ago, I began my second clinical trial, an immunotherapy trial, at Johns Hopkins under the direction of my amazing oncologist, Dr. Julie Brahmer.

If you are keeping track, 18 months post-diagnosis, I am now in my fourth treatment. These targeted treatments, like Zykadia, have allowed me to live a relatively normal and productive life. Thanks to these medical breakthroughs, I have been able to experience many quality-filled days with my family.

As a late-stage cancer patient, I am fully aware that I am kicking the can, so to speak. Luckily, I have honed my procrastination skills over the years, and with the right combination of science,

prayer, and the love and support from what we affectionately call Team Kennett, we fully intend to keep kicking that can from trial to trial until one day we can all celebrate a cure for cancer.

Again, I thank the Committee for holding this hearing and stand ready to answer any of your questions.

The CHAIRMAN. You all are amazing, all of you. Thank you.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman, and let me echo your thanks to our witnesses. This has been extraordinary testimony and very moving.

Dr. Varmus, you are a former head of the National Institutes for Health.

I strongly support more funding for biomedical research. I think it is one of the best investments that we can make. Even if you put aside the suffering that we can help alleviate, we should be investing because we are spending so much money on health care in this country, on illnesses that we can make real progress on if we were willing to increase NIH's budget.

What do you think we should be spending on a percentage basis?

I am mindful of the fact when I first came to the Senate a goal of our caucus was to double NIH spending over five years, and we did it, and then it went flat, and now it is down.

What should we be spending?

Dr. VARMUS. Well, thank you for the question and for the praise for our agency, Senator Collins.

This has been a traditional problem—deciding what kind of increases or what kind of budget NIH should receive. I think all of us who are in the business of leading this agency have felt that there is always going to be room for expansion, but expansion should be predictable and consistent.

Over the years, on average, the NIH budget has doubled in constant dollars every decade, but we have had a series of ups and downs that were in fact a concern of ours when the effort to double the NIH began in 1998. I remember very distinctly sharing concerns with members of Congress that we would have this very desirable rapid increase and that then attention would turn to something else and we would have a flattening of our budget, and that is indeed what has happened.

If we had a consistent increase, a super-inflationary increase, I would argue—as you know, there is a metric called BRDPI, Biomedical Research and Development Price Index, that tags our increases to a different inflationary rate, but I can tell you, as someone in the trenches of research, that even that inflationary metric does not really account for the increased costs of research because of the kinds of powerful technologies we now have at our disposal, but, if we had a consistent increase of about six or seven or eight percent a year, we would be ahead now of where we were even at the end of the doubling. I know all of us were hoping that at the end of the doubling there would be a continuation of the historical rate of increase.

Now we have a lot of catching-up to do. As you have heard, the estimates are that we are about 25 percent below where we were when the doubling began or, sorry, when the doubling ended, and that level is about comparable to 2000.

If we envision returning to that level over several years and then having a pledge to continue regular increases, I think we would be in good shape.

I have personally proposed that the appropriators, who, of course, would like a one-year appropriation so they have control of the budget, also at the same time as making a budgetary proposal, consider the planning of out years so that we are dealing with a rolling five plan. It might not be possible to agree to it when the time comes for appropriations, but at least we have some stability, some expectation, and, from the point of view of a scientist-administrator, knowing that is the general intention, helps dramatically because we do not do research in one year. Research projects are five or ten or fifteen years long.

Thank you for the question.

Senator COLLINS. Thank you.

That predictability, I think, is so important. I would actually like to see multiyear funding approved up front. I think that would be really helpful.

Ms. Dempsey, you were your mother's primary caregiver, and I know you had to become very familiar with different treatments, but it is extraordinary that she was able to fight her cancer for 17 years, and I am sure you were a real part of that.

Mr. Kennett also mentioned how important Team Kennett was, and has been, in his battle.

Could you talk a bit about the nonmedical treatments that the center provides that are so important to patients and their families.

Ms. DEMPSEY. Sure, thank you.

We like to think—I often speak about it from head to toe, which is a holistic approach. Certainly, support services are very important, but taking care of the whole person—the whole mind and body—is very, very important.

The whole family, not only the patient, but the caregiver, the children, anybody who has been impacted by cancer, also needs those support services, and that was part of the conception of the center—was the idea behind helping everyone, the patient included, but the entire family. Very, very important.

Senator COLLINS. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Varmus, have you had a really surprising discovery that when it started out you never would have expected?

Dr. VARMUS. I can give you many examples in the last—especially over the last five or ten years, but I would like to pick up on Chip Kennett's observation because it has been directly dramatized for you today in the story of his own cancer.

I, myself, work on lung cancer and the genetic basis of lung cancer, and I was astounded.

We think of chromosomal rearrangements, movements of one part of a chromosome to another, as a kind of abnormality that most commonly occurs in leukemias and lymphomas, but about 10 years ago, people working on the kind of lung cancer he has, who had no carcinoma of the lung, discovered that a certain subset of patients—about five percent, as he correctly stated—have a translocation in a solid tumor that takes a gene we knew a little

bit about because we had studied that gene in childhood leukemia. That gene makes an enzyme that we know quite a bit about, and it was being made inappropriately active as a result of the chromosomal exchange.

It was possible to go in just a few years, very few years, from that observation, which came about because people were just looking throughout the genome with these now powerful tools that we have and found that this gene which had not been implicated in cancer before was now inappropriately activated, and find drugs that were shown in early-stage clinical trials to be very effective at inducing a remission.

Unfortunately, as Chip knows, many of these drugs become inactive because the cancer is very wily. It is an evolutionary system that evades the repressive effects of the drug and generates new mutations that make the drugs not workable.

We have been able to outfox that in some cases by developing so-called second-line drugs that can even treat these drug-resistant forms of his inappropriately activated ALK kinase, and that second-line drug worked for a while.

Now we are thinking about other new ways to do things, and I think now he is experiencing the benefit of decades of studies of basic immunology. How does the immune system work? Why doesn't it reject cancers?

What we now know is that it is possible to get rid of some of the breaks on the immune system and to make the immune system work for us. That is what is happening now. He is getting an antibody which is going to block the way in which the immune system suppresses itself.

Suppressors are important, too, because we do not want to be reacting to our normal tissue, but, when a cancer arises and the immune system has the ability to react to an abnormal protein in a cancer cell, then we have an opportunity, so those three things—a new targeted drug for a new gene indication, a way of getting around drug resistance and a way to use the immune system—all happened in the last ten years.

We can extend life and make cancer a more manageable disease by taking—but we have got to make the investment in those basic aspects of research that are not necessarily going to pay off, but the risk-taking is worth it.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

Mr. Kennett said research saves lives. Ms. Harper said research dollars equal lives. I would like to pick up where Senator Collins was on the question about investments and investments at NIH, and I particularly want to just build the record a little bit here about the relationship between federal spending in long-term savings on health care.

You know, a few years ago, a NIH study found that in 2010 the Nation spent about $124 billion on cancer care. That is almost three times bigger than last year's sequester cuts, and it is 25 times bigger than the entire annual budget of the National Cancer Institute.

Dr. Varmus, I just want to start with a different way to think about this question. Can you comment on how much money we

could save the health care system if we could better prevent even one type of cancer?

Dr. VARMUS. Well, we can approach that question in a few ways.

Senator WARREN. Push your button.

Dr. VARMUS. I should know by now.

We can approach that in several ways. The NCI itself has taken the data on which you base the $124 billion of spending in 2010 and build an algorithm that is available online to show how much we spend on care for any of these cancers.

I think you have to add to that other kinds of potential savings. When people die at an early age or become incapacitated by cancer or can no longer work because of it, we have big, big expenditures there, too, that are very important to calculate.

Then people have their valuation of life, which is another thing we like to think about when we do the calculation of how much we would gain if we could reduce the frequency and reduce the cost of supporting someone who is going through cancer treatment.

The maximum, of course, would be the total amount of money we now spend, and we can give you those numbers for each type of cancer, and we can even divide that into the amount we spend when a cancer is diagnosed, when care is continuing and the latter stages of cancer journeys that end unhappily.

Senator WARREN. Yes.

Dr. VARMUS. It is possible to give you good numbers, but I think it is just overall important to emphasize the multiplicity of kinds of savings we could achieve.

Secondly is the fact that whenever these economic analyses are done we usually come back to the fact that the public, everybody, wants to be healthier. People do not want to have cancer, and that is hard to place a dollar value on, but it is an incredibly important aspect of what we do and what I believe the country should be investing in.

Senator WARREN. Well, I think that is a powerful answer that you give—a reminder that even the dollars we talk about that we currently spend in the health care system on cancer do not come close to identifying all of the costs, all of the out-of-pocket costs, much less all of the human costs, associated with it, but that makes it, to me, all the more mystifying that we have not increased our funding for NIH and that, in fact, as you rightly say, if we do a BR—what is it? DPI? That is right. I will get it right.

Dr. VARMUS. BRDPI. BRDPI.

Senator WARREN. That is right; that if we do even a modest inflation adjustment, that we are down somewhere between 20 and 25 percent in terms of spending since 2000.

As I understand it, right now, NIH is able to fund, has the resources to fund, only one in six of the research applications, but I want to ask you, Dr. Varmus, just to tell us; are the other five applications not worth funding?

What does this mean that we are now in a situation where only one is five research proposals——

Dr. VARMUS. At NCI, Senator, it is actually a little worse than that. We fund about 13 percent of the applications; that is, we turn down 87 percent.

Now, historically, I would not sit here and say every one of those grants should be funded. Historically, the NIH seems to function very well when we fund about a third of our applications. I say that in part because, as someone who has sat in review and who has overseen large numbers of grant applications, we can tell the top third pretty well.

When we have to dissect out of that top third the one out of three or so that actually get funded, we are in trouble.

Moreover, that number is slightly deceptive because new proposals often—as opposed to renewals—do not do as well and in very hot fields of research, where a lot of progress is being made, the rate of success may be even lower because there are so many applications that are being looked at.

I think it is just impossible, and there are data to support the idea that we are not very good at telling the top 10 percent from the second tier, the second 10 percent, of our applications, and we know that we are missing important opportunities.

We are seeing the ends of careers of people in whom the NIH has invested a lot of money because we generally paid for the training, either directly or through fellowships or through the support of students on grants, and, yet, people get to a certain stage in life, and then they are unable to get funded. The dean of the medical school does not like it when you do not get funding, and careers terminate in appropriately.

We are extremely concerned about the issues you are raising.

Senator WARREN. If the Chairman will indulge me for one more question, I would just like to ask Dr. Sellers if he would weigh in a little bit on the impact of underfunding the NIH and other medical research on the development of new therapies, new approaches, a more comprehensive approach to treatment in the cancer area.

Dr. Sellers?

Dr. SELLERS. One of the consequences of the exceedingly painful pay lines is that it promotes scientists who are in the business of science, right?

If you do not get your grants, the dean is mad; you are not going to keep your lab going.

To push for really boring incremental steps, we do not have time for that, right?

We need bold thinking. We need innovation. We need people to take some changes.

Not everything should be mad, crazy, out there, but we are doing such obvious next steps, incremental steps, because that is what the study sections have gravitated to—well, we know this will work; if we have got X amount of dollars to invest, we want to make sure that we get something out of it.

I think that is absolutely stifling the biomedical community.

I agree with Dr. Varmus's comment that you do not want to fund all of them, but we have gone to the other end of the spectrum, and we are funding incremental science rather than a nice balanced portfolio where we are swinging for the fences some of the times.

Senator WARREN. Well, I appreciate it very much.

Thank you, Mr. Chairman, for letting me go over my time.

I want to say thank you again to Mr. Kennett and Ms. Harper for getting out there and being advocates on behalf of better funding for NIH.

We can do more. We can do so much more, but we are all going to have to pull together on this and follow Senator Collins's leadership and the leadership of others on it.

Thank you.

The CHAIRMAN. Senator Ayotte.

Senator AYOTTE. I want to, first of all, thank the Chairman and Ranking Member for holding such an incredibly important hearing. This is an issue I think that has touched everyone's life at some point.

I am just honored to be here with my friend, Chip Kennett, and his wife, Sheila. They are incredible people. They come from New Hampshire, my home state, and Chip grew up in Conway.

His family is just an incredible family, who has been so involved in New Hampshire's Mount Washington Valley, and just talk about courage. Talk about just a role model for other people, to be here for your advocacy, Chip, but, you know, you meet some people in your lives that touch you, and Chip is one of those people, so it is great to have you, Chip.

I want to say the same thing for you, Ms. Harper. It was really inspiring to hear you talk about your battle with cancer. Thank you for being here.

I wanted to ask—let me just add the support that I have for my colleagues. This issue of investing in NIH and biomedical research is a bipartisan issue, and it is an incredibly important issue because this is an issue in terms of cancer, of finding a cure for cancer of all types that, again, hits Republicans, Independents, every—Democrats. Unfortunately, everyone gets touched with cancer, and this is something we all need to work together on.

I am honored to be here with my colleagues who I know are very committed to this issue as well, but one thing I wanted to ask you, Dr. Varmus, is I know that with the investment that is being made under NIH through your institute there are also research dollars that we are putting on other places like DoD, and how is the coordination among those research dollars, and what is your view on how—what should we be doing there?

Should we be continuing also to fund the DoD research or putting all those dollars under NIH?

Is that communication line good?

I was just thinking, making sure that we are maximizing our opportunities in terms of the research that we are doing.

Dr. VARMUS. Thank you, Senator Ayotte.

We, of course, are in touch with our colleagues at DoD, and we welcome research money that comes through a variety of channels. In fact, in addition to money that comes to cancer research through DoD, there is money that comes through other institutes of the NIH, through the Department of Energy and through many private and industrial channels as well.

If you look at the entire national cancer program, the NCI, of course, is the lead player, but there are many other private and public sources of money from states and other places, and we do pay a great deal of attention to all of these other channels.

In particular, of course our federal colleagues work closely with us, and we are well aware of what is going on at the Department of Defense through their breast cancer and prostate and other initiatives, just as my colleagues at the neurological institute at NIH are aware of the investments made through the DoD in neurological diseases.

I do not see a problem with this. I think it is important to keep track of it. Many of our scientists who are supported by NCI are also supported by the Department of Defense, and we welcome that co-funding because we are underfunding our investigators.

As I mentioned, science has gotten very expensive—and to run a very productive lab that uses our so-called high through-put intense technologies and make use of mouse models and do research with human subjects. The research is very expensive, and it may cost half a million to a million dollars or more for a laboratory to be productive and doing imaginative things.

Senator AYOTTE. Yes, I do not dispute that. I think that is incredibly important, that we invest more money in research.

I think what I wanted to make sure is that if we are investing at DoD that you are also coordinating that so that we are——

Dr. VARMUS. The coordination goes on not only at the administrative level, if I may interrupt. Scientists are aware of what other scientists are doing. They go to meetings. They exchange. They read the literature, which is quite open these days. I think there is a higher degree of interaction than some people often think.

Senator AYOTTE. Good. Well, that is really good to know.

The other issue is, obviously, Dr. Sellers, I heard you talk about 400 clinical trials that are ongoing at the Moffitt Center, and also, I know we have Mr. Kennett here who has been really participating in a number of clinical trials.

Do you feel that in terms of the approval process on the FDA that you are getting the support you need there to make sure that in these clinical trials that you are being able to really get things to trial that need to get to trial, that you are getting the type of cooperation you need on the FDA end, to make sure that we are not delaying getting life-saving drugs to market, that we are not delaying getting people who need to get in trials, in trials?

Just as I heard you talk about it, I just wanted to hit that issue, to see what the experience has been and what your thoughts are on that issue.

Dr. SELLERS. It takes longer than any of us would like to have a trial approved. You heard earlier about an example with the ALK inhibitors that was a success. When you have that compelling evidence, it is not burdened by the FDA to delay the approval.

There was recent approval of a combination treatment for melanoma, probably the most dramatic effect that we have seen for an incurable disease when metastatic, just in the past year.

The challenge is the running time it takes from the time of a discovery to the time it gets—we have a target—to clinical trial to completion; it has taken a long time.

To follow up on the example of the ALK inhibitors, what we are learning now because of the genetics of cancer is that it is not one size fits all, and so, if you were going to do a trial of lung cancer,

if only five percent carry that mutation, that trial would be a failure.

You really need to focus on the patient population that has the target for which that therapy will work, and that is where the work needs to be done right now—and the opportunity for us. We have the technologies to do the profiling.

I was shocked when—and your statistics were spot-on. Lung cancer is the number one killer.

The head of our thoracic oncology program says, Tom, lung cancer is a rare disease.

I said, Dr. Antonio, what are you talking about?

He said, when you think about it molecularly, we have got all of these different subsets, and the ALK inhibitors are not going to work for a lung cancer that does not have that particular marker.

That is where we need to do the science, to identify what are those driver mutations, get the right patients enrolled in the trial, and, when we can do that, we see that the approval goes very quick because the signal of benefit is much more evidence.

Dr. VARMUS. Can I just amplify a couple of points?

First of all, it is incredibly important to emphasize this notion that lung cancer is not one disease; it is many different diseases that happen to arise in the lung, in different cells, with different mutations.

Secondly, the FDA has a difficult problem. In my view, Richard Pazdur, who runs the oncology division, and his colleagues have been incredibly responsive to the changes in science that require considerations of companion diagnostic tests. The possibility of doing clinical trials as the NCI is now planning are inherently different in character because we do genetic testing first and then put patients into certain arms of the trial.

Third, to consider the use of two unapproved drugs in a combination trial.

These are new challenges for the FDA, which I believe they are responding to extremely well.

Senator AYOTTE. Thank you.

The CHAIRMAN. Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman.

Thank you, Ranking Member Collins.

Dr. Varmus, welcome.

All of you, thank you for your advocacy and for your work in this area.

You will recall, Dr. Varmus, we had a long ordeal getting through the Pancreatic Cancer Research and Education Act, which then ultimately morphed into the Recalcitrant Cancer Research Act, and that finally passed in 2012. It required that you all develop a scientific framework for a series of cancers that were not getting particular attention and that had not responded to the sort of general treatments that had been successful and, therefore, were deemed recalcitrant.

In February, you reported out the scientific framework for pancreatic cancer, and I want to thank you very much for that accomplishment.

You indicated in the framework that you planned to pursue four targeted research initiatives. Can you tell us a little bit more about the four targeted research initiatives.

Dr. VARMUS. Absolutely. Thank you, Senator, for both your advocacy for the work we do and for the question.

As Senator Whitehouse indicated, I would only quarrel slightly with the idea that we were ignoring pancreatic cancer when, in fact, the budget for pancreatic cancer research has gone up quite quickly over the first decade of the 21st Century.

Moreover, as you and I have discussed, a large amount of work we do on certain kinds of cancer genes and certain basic attributes of cancer are highly applicable to pancreatic cancer.

I recognize what a terrible disease this is. Indeed, today's New York Times has the obituary of a close friend of mine who died of pancreatic cancer three weeks after diagnosis.

I am totally with you in curing this.

Senator WHITEHOUSE. Thank you.

Dr. VARMUS. The first thing that we noticed in the workshop that we held to define the framework was a surprising phenomenon, that many patients who had been diagnosed with type 1 diabetes, within a year, developed—a significant number, higher than expected percentage, developed pancreatic cancer.

We are always looking for ways to diagnose this cancer at an earlier stage, and we have been—we are about to release, or we are considering and will expect to release, a request for proposals to study that relationship between diabetes and pancreatic cancer.

Secondly, at our workshop, we recognized that there are a lot of risk factors for pancreatic cancer that have been underappreciated—some rare genetic mutations that are inherited, cysts of certain kinds that predispose to pancreatic cancer, and we are setting up an activity which is not yet fully formed to try to pursue that more effectively.

Third, we are interested in doing more work on the immune response to pancreatic cancer, and there are many things that are in the works now, including some recent publications, that show the activity in this area that we are pursuing.

Fourth, we discussed the importance of a mutation in another gene that has not yet been described here, a gene called the K–Ras gene, which is mutated in over 95 percent of pancreatic cancers and is a powerful driver of pancreatic carcinogenesis.

Moreover, that gene is mutated in a very large number of other kinds of cancers, including lung adenocarcinoma at 30 percent and in colon cancer, where 50 percent of patients have that gene mutated.

We have reengineered our budget at the Frederick National Lab for Cancer Research out in Frederick, Maryland and recruited an outstanding scientist, who used to be the director of the Comprehensive Cancer Center funded by the NCI at University of California-San Francisco, to lead an international effort, which is now well underway, to try to understand this gene.

If we could make progress against this so-called K–Ras gene, which has been implicated in pancreatic cancer for 30 years, we would have a tremendous impact, I believe, on treatment of many kinds of cancer.

This activity, which is both housed and centralized at Frederick but also engaging scientists all around the world in a six-pronged effort that I could describe to you in more detail, I think has a great chance of changing the landscape in this important area.

Senator WHITEHOUSE. Thanks.

One last question. You came in ahead of the statutory deadline. I appreciate that.

Dr. VARMUS. We were—right.

Senator WHITEHOUSE. You came in, in February, and it was not required until July of 2014.

There was a statutory requirement for benchmarks for progress by July 2014. Do you think you will meet the deadline for the benchmarks for progress by the deadline?

Dr. VARMUS. Yes, we will make that deadline.

We will also make the deadline for reporting to you on a second difficult cancer—small cell lung cancer, a lung cancer but, again, different from the lung cancers we have been talking about, one that has a really very dismal outlook and we do not understand very well.

It has been my view, because it has been difficult to study this kind of lung cancer, there has not been enough investment in it. Sometimes these things are not willfulness on the part of NCI leadership. It is a question of where the scientific opportunities are, which scientists are willing to work on these problems as opposed to another problem that is more accessible.

Senator WHITEHOUSE. Yes.

Dr. VARMUS. We think we see some new ways to pursue small cell lung cancer, and I am hopeful we will have a report as effective as our pancreatic cancer report to you by the next deadline.

Senator WHITEHOUSE. Terrific. Well, we are thrilled with your work and applaud your successes and would like to urge you forward in more meaningful ways than just urging you forward.

Dr. VARMUS. We would appreciate that, Senator. Thank you very much.

Senator WHITEHOUSE. We hope we can put the dollars behind our enthusiasm.

The CHAIRMAN. Senator Whitehouse was very kind, along with Senator Blumenthal, to have a regional hearing for us up in Connecticut over the issue of insurance companies dropping providers—namely, doctors, hospitals—from their plans.

This happened to Dr. Sellers at the Moffitt Cancer Center. An insurance provider under Medicare Advantage, which is HMOs for Medicare—that is an insurance company, an HMO—dropped them as a provider.

Obviously, the impact on the patient in a treatment, to suddenly find out that you have lost your doctor or you have lost, in this particular case, an entire research clinic is devastating.

What did you learn, Dr. Sellers, about the impact on the patient when the insurer tells them that they cannot continue going to the same doctors for their cancer treatment?

Dr. SELLERS. That was the most unfortunate experience. It caught us, as an institution, a little bit by surprise when this happened.

The patients were not happy. They happen to have a very strong relationship with their doctors and their care providers. People love our nurses at Moffitt.

I think it is Nurses Week or Nurses Month or something, so we need to give a shout-out for the nurses.

It is a challenge, and it is unfortunately a symptom, I think, of the health care environment—the moving target.

In our understanding, it was an expensive program for that insurance company to offer, so they were very clear that was something they did not wish to continue.

The CHAIRMAN. Some of them came back, and some of them did not come back; is that right?

In the meantime, the toll, emotionally, physically—that aspect of hope that you talked about, Ms. Harper.

Dr. SELLERS. I think when a cancer patient is in a battle, that is the last thing that you need—is the distraction of an insurance company saying, no, you cannot see your doctor anymore, but that is something we absolutely should not allow.

The CHAIRMAN. Years ago, Ms. Harper, in her show, was in the portrayal of entry of women into the workforce. Now women, in the meantime, have made tremendous strides in their professional careers and the workforce, and, yet, some studies have shown that women in the workforce with cancer face employment issues years later after their diagnosis, and so put that in context for us, Ms. Dempsey. You have dealt with that.

Ms. DEMPSEY. As I sit here, I am trying to sit quiet because I just want to hit this button and respond to every single one of you.

Not to lessen your question, but may I say—and this could be a leaving remark, so you can put it on the end—that perhaps we should adopt Amanda Dempsey's mantra, which is one step at a time, one day at a time and keep moving forward?

We ran into clinical trials that were not quite available constantly as mom had recurrences, and it was very frustrating because mom would have accepted the clinical trials regardless of them being FDA-approved.

I am hearing a lot of the same difficulties, so it is very enlightening.

I think we just need to keep moving forward and do it together.

The CHAIRMAN. All right. In the Journal of Cancer, researchers at the University of Michigan found that women diagnosed with breast cancer, who eventually go on to receive chemotherapy, face a higher likelihood of unemployment over time.

Anybody want to comment on that? [no response]

Okay, Dr. Sellers, Moffitt's work on geriatric oncology. You have made quite a few contributions. What can be done to encourage more geriatricians to engage in this research activity?

Dr. SELLERS. Well, I think that the geriatricians are aware of cancer as a problem and they are going to be more involved.

We need to get better coordinated care to have the geriatricians who are able to do the functional assessment—what is the patient able to do, their nutritional status, their mental status, their functional abilities, can they walk, can they move heavy weight.

Getting them working carefully with the rest of the medical team that would deal with the cancer—it has to be a partnership, and

that is something that I think is the reason why our Senior Adult Oncology Program is where it is. It is because we work in a multidisciplinary team and take that into consideration.

The CHAIRMAN. Ms. Harper—first of all, Dr. Varmus.

Dr. VARMUS. No, I am happy to let Ms. Harper go first.

Ms. HARPER. No, answer.

The CHAIRMAN. Do you have a response to that?

Dr. VARMUS. I do because there are a number of ways in which the NIH is trying to foster exactly what you have espoused; that is, getting people who study aging to think more about the effects of aging on cancer.

We have a very close relationship with the National Institute on Aging. We are part of what they call their GeroSciences Group. We have a number of clinical trials that are specifically focused to aspects of aging and cancer.

We are trying to understand one interesting phenomenon—that cancer incidence often falls at very advanced ages. What is it about the aging human being that may result in some decrement in cancer incidence?

Then there are questions about the basic biology of aging—mutation rates, the failure of the immune system in aging, and the changes in the hormonal and environmental atmosphere that surrounds cells that are potentially targets for cancer-causing processes that influence the frequency with which cancer arises in older people.

We do believe that the traditional bread and butter of this Committee, studying the aging process, is very closely intertwined with what we are trying to learn about cancer.

The CHAIRMAN. Thank you.

Ms. Harper, in your testimony, you talked about alternative medical options.

I have a good friend who was going through the traditional medical route and then went very successfully with the alternative route and is now back on the medical route.

You want to—how did those treatments work together to be healthy for you?

Ms. HARPER. My doctor——

The CHAIRMAN. Push the microphone.

Ms. HARPER. Chairman Nelson, thank you for that question because every cancer patient is different. That is what I have learned—and when the doctor said there are many kinds of lung cancer.

My doctor, Natale, Ron Natale, he is a wonderful clinician and also a researcher. He said, you know, the acupuncture and the idea of taking traditional Chinese medicine, granules or tea; he said, that is fine with me, and then I asked him about another thing for growing hair. I was losing a little. I have been lucky so far, and he said, no, no, do not do that. It contains a hormone that might not go with what you are taking.

I say do everything within your own reason.

I have received so many letters and texts and prescriptions.

Most recently, I was having—it had to be canned asparagus, ripped up three times a day in a blender, and I was to drink that.

My husband, who is very healthy, said, why wouldn't it be fresh asparagus?

I mean, honestly.

There was some mud I was supposed to take from an Indian reservation, put it into a capsule and take that, and it is loving, and I appreciate it, and I get what they want—me to be well, but you really have to watch.

The CHAIRMAN. Understood.

Ms. HARPER. Yeah. I stayed with—my oncologists are fabulous, and Natale has told me. He said, Valerie, what you have I have never seen in 30 years, which is leptomeningeal so active without it in any other part of your body.

I am going the traditional medicine way. It has worked, and when my, you know, three-month to six-month happened—the diagnosis was in January of 2013—I can only say maybe it is the meridians opened by the ancient Chinese; maybe it is the pills I am taking, which are wonderful.

They were just developed four years ago—the drug I am on. I am on two, and, no more chemo. My doctor does not do it.

I have kind of been working. I think that is what people have to do—listen to their own heart and sense, but also do try it. Try what might keep you alive.

Yes, please.

Dr. VARMUS. I just want to emphasize one important part of your story—that you talked to your doctor about what you were doing.

Ms. HARPER. Oh, yes.

Dr. VARMUS. At my days as head of Memorial Sloane Kettering, the things that were often conducive to side effects of drugs that were being taken through conventional medicine were the surreptitious taking of other kinds of things.

Ms. HARPER. Yes, absolutely.

Dr. VARMUS. If you do things that are alternative, I would just emphasize to all cancer patients——

Ms. HARPER. Oh, yeah.

Dr. VARMUS. [continuing]. To talk to their oncologist to be sure we do not have an intermingling of substance that result in toxicities that are very difficult to explain without information.

Ms. HARPER. You have to take responsibility for your own health and keeping your hope up and saying live in the moment. If you are worrying about dying, you have missed the moment.

I miss her beautiful coral jacket if I am here saying I am going to die in a month; do you know?

I just picked that out, Senator Collins, because there is so much joy and beauty and many wonderful things in life.

If you are living, do not go to the funeral until the day of the funeral, and we are all terminal, and this young man is spectacular. He touches my heart so deeply because of the courage and the forward motion of his life, not just for himself but for his children and his wife, and what you said was great. The hope is very important; also, active engagement in the fight.

I am sorry I talk too long.

Ms. DEMPSEY. Because you are living with cancer.

Ms. HARPER. Yes.

Ms. DEMPSEY. You are living every day.

Ms. HARPER. Yes, you live while you——
Ms. DEMPSEY. Living forward.
Ms. HARPER. Yes, exactly.
I hope I answered your question.
The CHAIRMAN. Thank you.
Ms. HARPER. Good.
The CHAIRMAN. I hate to bring this to a close, but within a few moments we are going to have to leave to vote because a vote has been in progress already for six minutes.

Dr. Varmus, I want to end up with asking you; we are worried, as we have studied the effects of the ACA, about a physician shortage. Now how is that going to affect you in oncology physicians and researchers? How are we going to able to provide the numbers?

Dr. VARMUS. Well, there are a couple of questions. I am not an expert in medical economics, but I can tell you a few things that are obvious.

One is that the number of cancer cases is rising. Even though the incidence, when age-adjusted, is going down, the burgeoning of the older population, as I mentioned earlier, is accounting for a big increase in the number of cases, so we are going to need more oncologists.

Secondly, we are going to need—if we are going to treat people more effectively and treat them more—and try to drive down cancer rates and cancer mortality rates, we are going to need more cancer research, and we have had a long discussion already today about how the funding of biomedical research is going to affect our ability to recruit the best people to work on that problem.

Then, of course, the economics of the marketplace are going to be influential in determining where the most talented physicians go to practice, and I think we need to be aware of how those rates will influence people in the future.

We are hoping that by providing much more effective ways to treat patients, we not only benefit patients, but we attract much better physicians to come into the field of oncology because right now, I think, is just one of the most exciting things to do because it is changing all the time.

When I hear Chip Kennett's story, I see layer after layer of new opportunity for finding new ways to treat his disease, and that cannot be anything but exciting for a physician who is trying to take care of you and do what you want, which is to have a good outcome. We are trying to provide through science the hope and the opportunity to make that outcome a good one.

The CHAIRMAN. I want to, just before we close out, put the backdrop to this whole thing of the discovery of these wonder drugs. A three to six-year period of drug discovery and pre-clinical, and then a six to seven-year period of phase one through three of the clinical trials, and then the FDA review, and then the approved drug, and that is another half-year to two-year period—so we are talking about a long continuum of time.

Senator Whitehouse.

Senator WHITEHOUSE. I yield to Senator Collins.

The CHAIRMAN. Okay, Senator Collins.

Senator COLLINS. As some of my colleagues know, I have never missed a vote, so this is making me very nervous as this vote ticks

on, but, for the record, I am going to submit some additional questions because I am really interested in Ms. Dempsey's comments on how it was to find clinical trials for her mother.

I would love to know the experience of Ms. Harper and Mr. Kennett in how did you locate the kinds of treatment that has been successful for you because I think that is really difficult for a lot of patients who do not have your expertise or your persistence or your hope or your contacts, so that is something I am going to submit for the record.

To Dr. Sellers and Dr. Varmus, I am going to submit questions to you on whether we have too many silos in our research or whether there is good sharing. The reason that I want to hear your opinion on this in writing is I have always thought that if the Federal Government is financing it, boy, it ought to be shared.

Maybe I am naive about that. Maybe there is more to this, but I do not want there to be silos.

I want to make sure that researchers get the advantages of other researchers' work if it is federally funded. If we are all paying for it, let's make sure that it is shared.

Most of all, I want to thank each and every one of you for being here today, for giving me hope and for your extraordinary testimony. It really was a wonderful hearing.

I thank you, Mr. Chairman.

I am now going to run to the Senate floor. Thank you.

The CHAIRMAN. You have three minutes to vote.

Senator Whitehouse.

Senator WHITEHOUSE. I will be extremely quick.

I just wanted to thank you for raising this question of the provider networks with Dr. Sellers. There are obviously very good reasons for limiting provider networks—in order to build a network of coordinated care, of linked HIT support, of accountability, to quality metrics and outcomes metrics. It is all terrific.

There are also some bad reasons to do it, like for negotiating leverage. If you will not give me a good price, I will cut you out of my network. Even worse, you have a lot of expensive patients; so I do not want you in my network, and, until we can work on making sure that these insurance companies are being transparent about why they are doing it, we are going to continue to have problems. I hope it is something we can continue to work on, and thank you for raising it.

The CHAIRMAN. We can have a hearing on just that subject, because we have got to race out of here to vote, we give you our love; we give you our appreciation, and we thank you for a most illuminating hearing.

The Committee is adjourned.

[Whereupon, at 4:01 p.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements

Testimony
Before the
Special Committee on Aging
United States Senate

Statement of
Harold Varmus, M.D.
Director
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

Wednesday May 7, 2014

Mr. Chairman, Senator Collins, and others:

I am pleased to appear today on behalf of the National Cancer Institute to discuss the relationship of cancer to aging.

It is an opportune moment for this discussion. Thanks in large part to improvements in health care, life expectancy has been extended at unprecedented rates, both in our country and around the world. The number of people over age 65 is growing especially rapidly in countries like the United States that experienced sharp increases in birth rates shortly after World War II, nearly 70 years ago. Furthermore, significant progress is being made in cancer research, with a much deeper understanding of the nature of this complex set of diseases and with improvements in the way we prevent, diagnose, and treat many kinds of cancers. Hence, there is both a need and an opportunity to address more effectively the problems presented by cancers in the elderly.

Because most types of cancer—but not all—are commonly diagnosed in older age groups, the number of people with cancer is rising, and will continue to rise, here and globally. This chart (the only one I will show) displays both the current and anticipated future distribution of new cases of cancer, grouped by age range, in the United States. As you can see, the absolute number of cases will rise from about 1.7 million today to about 2.5 million by 2040. The majority of new cases already occurs in three age groups—65 to 74, 75 to 84, and 85 or greater. The proportions will increase in all three groups over the next thirty years, assuming that current patterns are maintained, with little change in the younger groups. Of course, we aspire to change those patterns with

more effective means to prevent cancers. But the pace of such change is inherently slow, in part because cancers develop over many years, not days or months.

As the elderly population grows and our ability to treat cancer improves, we are also observing greater numbers of people, especially among the older age groups, who are survivors of cancer. Cancer survivors are people who have had a cancer diagnosed at anytime in the past, whether or not they remain under treatment or have evidence of cancer currently. At present, there are over 13 million cancer survivors in the United States, up from about three million in the early 1970s, and the number is expected to rise to about 18 million by 2020. More than half of these people are over 65 years of age, and that older group will experience the major increase in numbers.

During the next several minutes, I will summarize what we know about the biological basis of the relationship of cancer to aging; what can now be done to prevent, detect, and treat cancer more effectively, especially among the elderly; and how the NCI and its research community plan to expand our knowledge of the relationship of cancer to aging, in hopes of reducing the burden of cancer among those at advanced ages.

In considering all of these topics, it is important to keep in mind the special vulnerabilities of older individuals—including, in particular, co-existing medical conditions (referred to as "co-morbidities") that can shorten life independently of the effects of cancer and can complicate delivery of cancer therapies.

The relationship of cancer and aging

Overall, cancers are diseases caused by accumulated changes, mostly mutations, in a cell's genome. Since those changes accumulate with age, the incidence of cancers also increases as people age. Further, the number of cases in each country rises as life expectancy increases, even without any increase in the incidence (or rate of occurrence). This is a large part of the reason why cancers, as well as other non-communicable diseases, have recently become major causes of morbidity and mortality in the developing world, where overall life expectancy is rising rapidly.

To distinguish between changes in the age distribution of a population and changes in our ability to prevent and treat cancers, it is important to monitor progress against cancer by reporting rates of incidence and mortality, adjusted for changes in length of life, not simply by counting the numbers of cases. Furthermore, the relationship of cancer to age is not simple: not all cancer types show an increased incidence with increased age.

Recall that there are many types of cancer, and these types arise in different kinds of cells and in different organs. Moreover, we now know that these different cancers generally carry different constellations of changes in DNA. This means that the incidence of each cancer type is influenced by the numbers of cells at risk of becoming cancerous in each organ at different ages. The risk of developing cancers of different types is also affected by the degree of exposure to environmental agents that cause mutations; by gene variations inherited from one's parents; by the function of the immune system, which itself appears to weaken as we age; and by the availability of methods that prevent cancers or detect abnormal cells before they become fully malignant.

In view of these varied factors, it is not surprising that types of cancer vary with regard to the time of onset. Most dramatically, some cancers—like retinoblastomas, some leukemias and lymphomas, and some brain and bone cancers—are largely confined to children, adolescents, and young adults. In contrast, the median age of onset of most of the common cancers is between the ages of 61 and 72, consistent with the more general conclusion (reflected in the chart) that over half of all cancers are diagnosed in older age groups. There is one further complication: while most findings argue for increasing rates of cancer with increasing age, the age-adjusted rate (or incidence) of many cancers appears to fall at highly advanced ages.[1]

I will say more in a few minutes about some of these perplexing—and potentially informative—relationships between age and cancer incidence. But I want to conclude this segment of my testimony by reminding you of the dominant facts and their implications. First, the U.S. population is rapidly aging. The numbers of people over the ages of 65, 75, and 85 will all increase markedly over the next three decades, with nearly a doubling of the number over 65 and nearly a tripling of those over 85. Second, even now over half of all cancers are diagnosed in people over the age of 65, so age must be viewed as a major risk factor for cancer, along with use of tobacco, excessive exposure to other carcinogenic agents, and inheritance of certain genetic variations. Thus the number of cancer cases is likely to rise significantly over the next few decades in this country and around the world.

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[1] http://wonder.cdc.gov/cancer.html

Preventing cancer as people age: risk assessment, screening, early diagnosis

For people of any age, the first line of defense against cancers and their damaging consequences is prevention. Prevention encompasses at least four strategies: the methods (behavioral change or vaccines) that avoid cancer-causing agents or conditions, like tobacco use, obesity, or infection with certain viruses; an assessment of inherited genetic risk; the screening procedures that detect abnormal cells before they develop into life-threatening cancers; and the long-term use of drugs, as proposed for aspirin, that reduce the incidence of certain cancers.

Some of these have attributes that are particularly relevant to today's discussion of cancer in older populations. I want to mention three of these: tobacco cessation, screening methods, and aspirin use.

(1) It is widely known that use of tobacco, especially cigarette smoking, is the major avoidable risk factor for several types of cancer, especially lung cancers. Nevertheless, the health benefits of stopping tobacco use in middle age are underappreciated, and the benefits of stopping at more advanced ages have been inadequately studied. A recent review by Jha and Peto (New England Journal of Medicine 370:60, 2014) points out that even long-term smokers can relatively quickly regain several years of life-expectancy lost by active smoking when they stop at age 50. However, not enough information is available about elderly people who have recently stopped smoking to know how significant the benefits would be at higher ages.

(2) Screening tests have been developed for several common types of cancer—such as breast, skin, cervical, prostate, and colorectal cancers—but the use of those tests has often been controversial because of uncertainties about cost-benefit ratios and about the ages at which screening should commence or be concluded. Some common tests—such as the Pap smear for cervical cancer and colonoscopy for colorectal cancer—are not routinely recommended for people over certain ages (65 and 75 in the two instances mentioned), because there are harms (direct effects, such as colon perforation during colonoscopy, or over-diagnosis and over-treatment), as well as the obvious advantages, associated with most screening tests; because overall life expectancy (and hence benefit) declines at increasing age; and because certain cancers (such as cervical cancer) are less frequently diagnosed at advanced ages.

For some tests, there is simply inadequate information to make an evidence-based recommendation. For example, use of helical CT scanning for lung cancer is now being adopted in the United States, with guidelines based mostly on the findings from the

NCI's Lung Cancer Screening Trial (New Engl. J. Med 365: 395-409, 2011). In that trial, subjects were smokers or former smokers in good general health between the ages of 55 and 74 at the start of the study. Hence, it is difficult to make recommendations for individuals over the age of 74 or for those with co-morbid conditions, a common situation among tobacco smokers. Current guidance, based upon statistical modeling rather than direct evidence, suggests lung screening until the age of 80, but additional studies will be required to make secure recommendations for still older populations.

(3) Extensive pooled analysis of several studies of people who have taken low-dose aspirin for many years shows a highly significant reduction in incidence and mortality of several types of cancer, including gastro-intestinal and lung cancers (Lancet 377:31-41, 2011; 379:1602-1612, 2012). However, adoption of long-term chemoprevention of cancer with aspirin has been limited by concerns about the major side effect—gastrointestinal bleeding—especially in older individuals. NCI is collaborating with the National Institute on Aging (NIA) on a five-year study of aspirin's preventive attributes and side-effects in 19,000 individuals over age 65 in the United States and Australia, in hopes of providing information that will better guide the use of aspirin for chemoprevention.

Treating cancer appropriately in older patients

Historically, there has been a tendency to use less aggressive therapies in older patients with cancer, but that approach has been changing in response to several observations. First, many have noted the importance of distinguishing between chronological age (one's age in years) and physiological or functional age, especially in the oldest population groups, when making decisions about a therapeutic strategy. Patients who have a high chronological age are often resilient physiologically and able to withstand the rigors of most aggressive forms of cancer therapy.

In current practice, elderly cancer patients who are otherwise in good health—unlike those with severe co-morbidities or advanced neurological deficits—are now likely to receive surgery, radiotherapy, and/or drug therapy indistinguishable from that provided to relatively young patients.

This is being done because ample evidence suggests that healthy but chronologically old patients are capable of withstanding such therapies; because improved methods exist for controlling the symptoms (such as pain, nausea, and bone marrow suppression) that often accompany cancers or cancer treatment; and because benefits from rigorous therapies have been well documented in patients of advanced age.

Moreover, it is anticipated that fewer side-effects of cancer therapy will occur as improved surgical methods are developed, radiotherapy is delivered with greater precision and better division of doses, and drug therapy shifts from traditional chemotherapy to the more targeted approaches of "precision medicine". In addition, the several new immunotherapies—from the use of therapeutic antibodies to methods to strengthen the activity of immune cells—may be quite well tolerated by patients at advanced ages.

To obtain the evidence that supports the use of these therapies in elderly patients, it will be essential to insure that such patients are included in clinical trials. However, about two-thirds of patients in clinical trials are 65 or younger, even though over half of cancers are diagnosed in patients over 65. Despite some increases in the numbers of patients aged 65 to 75 who now participate in trials, the numbers of patients over age 75 who are enrolled in trials remain low, in the range of 10 percent or less. These numbers reflect the prevalence of co-morbidities that may disqualify such patients from enrollment; the difficulty of travelling to the sites of trials; and a persistent prejudice against inclusion of very old patients in trials. These factors require further examination, and the newly reorganized National Community Oncology Research Program (NCORP) is committed to studying patients at older ages and with the common co-morbidities.

Social and psychological aspects of the care of older patients, including the heavy burden often placed on familial caregivers, also deserve increased attention. It is often no easier to make decisions about when to abandon aggressive, curative measures in favor of symptomatic care and referral to hospice for aged patients than for younger ones. These decisions have important effects on quality of life and on economic costs of care.

Learning More About Cancer and Aging

Because NCI studies cancers of all types and because most cancers occur predominantly in older people, NCI is inherently heavily invested in research on this major cause of morbidity and mortality in aging populations. I have already mentioned a number of ways in which our research specifically addresses the relationship between cancers and aging: through studies of the epidemiology of many kinds of cancer; through efforts to address the utility of preventive measures, like daily aspirin, in older patients; and through attention to the numbers of elderly patients in our clinical trials. Furthermore, we use CISNET (NCI's Cancer Intervention and Surveillance Modeling Network) to analyze existing data and make predictions about optimal use of screening

tests, such as helical CT scanning for lung cancers. And other commonly used agents, like metformin for diabetes and statins for lowering blood lipids, as well as aspirin, are being studied for their possible chemo-prevention activity.

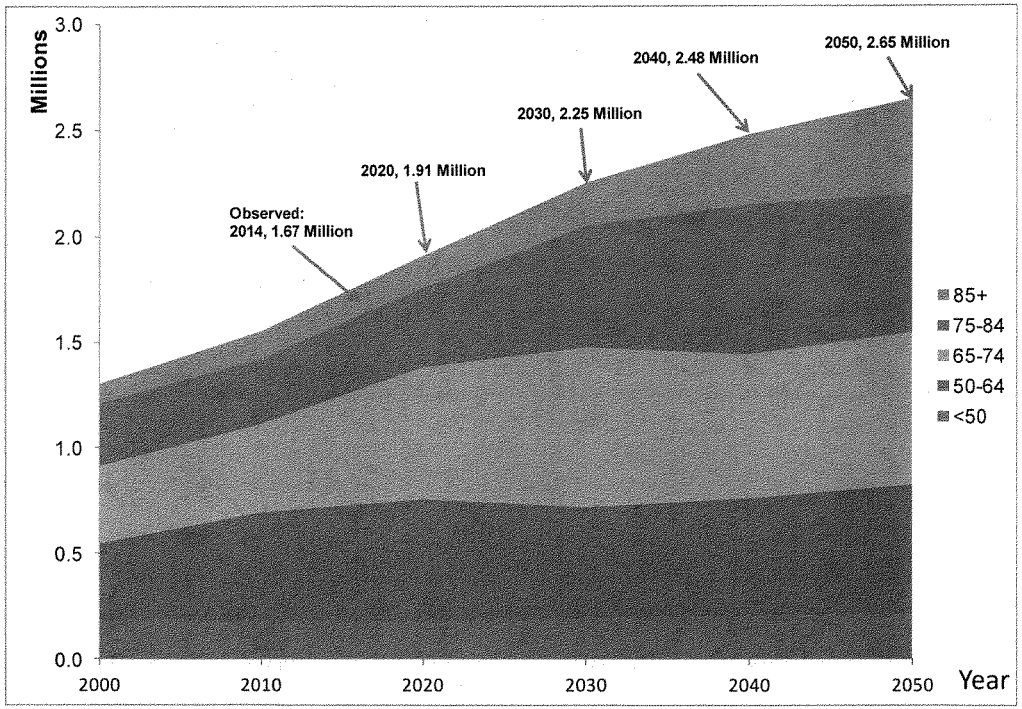
NCI is also supporting work on more fundamental aspects of aging and its relationship to cancer. For example, NCI's Provocative Questions initiative has called for applications to study how life span relates to cancer incidence in animals, starting from the observation that certain short-lived animals, like mice, have relatively high rates of cancer, whereas some much longer lived animals, like naked mole rats or reptiles, have very low rates. Other Provocative Questions ask how biological mechanisms might influence susceptibility to cancer risk factors at different stages of life or what aspects of aging, other than mutations, might promote or protect against cancers.

Other features of the biology of aging are also under investigation. The lengths of telomeres, the specialized DNA sequences at the ends of chromosomes, have been implicated in aging and carcinogenesis by many investigators, and both NCI and NIA have significant investments in telomere biology. The immune system is known to undergo functional changes with aging, and (as mentioned earlier) there is renewed interest in immunotherapies for cancer, so NCI is interested in effects of waning immune potency on cancer incidence and on opportunities for therapeutic intervention in older populations. New technologies allow a detailed description of an individual's microbial population, and numerous ideas about the contribution to diseases like cancers made by the microbes we carry during life, including late life, are being tested. Genetic diseases associated with premature aging ("progerias") have recently been examined for cancer incidence; some do not show increased rates of cancer, while those (like Werner Syndrome), characterized by high mutation rates, do. Studies of the effects of aging of mutation rates in different cell types and of the consequences of exposures to known carcinogens are among some of the other aspects of NCI's research program on aging and cancer.

One especially intriguing observation is the inverse relationship between cancer incidence and a diagnosis of degenerative neurological diseases (such as Alzheimer's and Parkinson's Diseases) that are common at advanced ages. In other words, compared to the general population, people with those neurological diseases are less likely to develop cancer, and vice versa. This observation forms the basis of yet another Provocative Question and has attracted the attention of other NIH institutes as well.

Finally, NCI has assembled or joined standing groups of investigators dedicated to the problems posed by aging and cancer, such as TRAC-I (Translational Research at the Aging and Cancer Interface), the Gerosciences Interest Group, and the Chronic Inflammation and Age-Related Disease group. I would be pleased to respond to any questions you might have.

Projected Number of US cancer cases for 2000 through 2050 based on projected census population estimates and age-specific cancer incidence from cases diagnosed in 1995-1999 in the SEER and NPCR areas.



Source: Annual Report to the Nation, Featuring Implications of Age and Aging on U.S Cancer Burden, Cancer, 2002.

Testimony of Valerie Harper, Actress and Cancer Survivor
U.S. Senate Special Committee on Aging
May 7, 2014

Good afternoon. My name is Valerie Harper and I'm very pleased to be joined by my husband Tony Cacciotti. We're both honored to be here.

I am a lung cancer survivor.

Chairman Nelson, Ranking Member Collins and other distinguished members of the Committee, thank you for inviting me to share my story today and to discuss a topic about which I have become quite passionate: funding for cancer research, particularly lung cancer.

Five years ago, March 2009, I needed surgery on my left wrist to repair an injury. I underwent the required pre-surgery chest x-ray, which shockingly revealed something was in the top lobe of my right lung that shouldn't be there. The wrist surgery was immediately put on hold, and the spot in my lung was diagnosed as a Stage 2 cancerous.

Thankfully, my surgeon at Cedars Sinai, Dr. Robert McKenna, in 1992, had pioneered a truly brilliant lung surgery procedure, Video Assisted Thoracoscopic Surgery, or VATS. It's like arthroscopic knee surgery – but for the lung. There was less bleeding, a much quicker recovery. And tiny scars because it's minimally invasive.

Every 6 months since that surgery in 2009, my lungs were scanned for any sign of recurrence. My lungs have been free of lung cancer – I was surgically cured of lung cancer! For 4 years.

But then in January 2013, there it was again, in a new form – Leptomeningeal Carcinomatosis, known as lepto, a rare and incurable cancer that occurs in the membrane that surrounds the brain. It took over a month of testing to conclude that my lung cancer had returned – not to my lung but to the lining of my brain.

Cancer reminds me of a very bad but tenacious performer, who although no one wants to see, insists on doing an encore, having a return engagement, making a comeback and worst of all, going on tour. In my case, so far, it seems to be held at bay under the watchful eyes of my oncology team, Dr. Ronald Natale and Dr. Jeremy Rudnik. I take my prescribed medications religiously, have regular brain scans and whole body testing twice a year to see if the cancer has moved. I also take TCM (traditional Chinese medicine) tea, have acupuncture and engage in visualization ridding myself of cancer.

Questions I have asked myself include why did I get lung cancer? And what would have happened to me if it wasn't discovered accidentally? But let's talk about the facts for a moment first:

1. Lung cancer is the #1 cancer killer in the United States among both women and men.
2. More than two-thirds of all lung cancers occur among never or former smokers, although the majority are among former smokers.
3. Lung cancer can also be caused by being exposed to secondhand smoke, air pollution and radon. Radon is a colorless, tasteless and odorless gas that causes lung cancer.
4. Genetics also play a role in developing lung cancer.

While I never smoked, I was exposed to secondhand smoke for decades. My mother also developed lung cancer, died of it. She too never smoked. So I had two risk factors – secondhand smoke exposure and possibly my genetics.

But that still begs the question. Why must most lung cancers be found by accident as opposed to having a reliable method for early detection? While I am grateful the x-ray revealed the cancer, it highlights a troubling fact in lung cancer: seventy-five percent of all lung cancers are found too late – at later stages once the disease has already spread. As a nation, we must prioritize health funding and funding for research and that starts here in the Congress.

In my capacity as a lung cancer survivor, I've gotten involved with the American Lung Association. They advocate for increased federal funding for the National Institutes of Health, including the National Cancer Institute. And while I won't pretend to understand the federal budget, I do know "research dollars equal lives."

There have been many recent exciting advancements in fighting lung cancer over the last few years. Tumors can now be tested for genetic markers that can lead to personalized treatments like I'm receiving. Landmark research conducted by the National Cancer Institute in the last decade has led to the U.S. Preventive Services Task Force awarding a "B" grade for screening people for lung cancer if they meet the definition of "high risk." Starting January 1, many people at high risk who have private insurance will be eligible for screening at no cost. Medicare is currently in the midst of a process to determine whether they will cover this screening for high risk individuals as well. But this is only a first step.

Research is desperately needed for early detection of the disease in people who aren't at high risk for developing lung cancer – people like me. Thank god I broke my wrist and needed surgery. Luck is not an acceptable substitute for early detection.

Research on new treatment options are also needed for when lung cancer is detected in stages 3 and 4. Chemo remains the first line treatment for many lung cancer patients, despite its difficult side effects. For 20 percent of lung cancer patients with a known genetic marker,

personalized treatments are available which are less toxic and more effective against specific tumors but more work is needed on biomarkers and targeted therapies.

But how can these investments in lifesaving research occur when all we hear from Washington is about cutting spending? We must stop thinking of spending and start thinking of investments. Meaningful increases in federal research investments are desperately needed to improve early detection and treatment options.

Last week, the head of the National Institutes of Health, Dr. Francis Collins, appeared before the Senate Committee on Appropriations and said – and I quote – "'The worst thing you can do for biomedical research is this 'feast or famine,' where you rev up the engine or you take away the fuel."' This of course applies to lung cancer research as well. Sustained investments in funding for cancer research will win our race against lung cancer.

Thank you again for the opportunity to speak with you today.

Testimony
Before the
Special Committee on Aging
United States Senate

Statement of
Thomas Sellers, MPH, Ph.D.
Executive Vice President and Center Director
H. Lee Moffitt Cancer Center and Research Institute
Tampa, Florida

Wednesday May 7, 2014

Chairman Nelson, Ranking Member Collins, and the Members of the Committee:

Good afternoon. My name is Dr. Thomas Sellers; I serve as the Executive Vice President and Director of the Moffitt Cancer Center in Tampa, FL. I am an active scientist and have maintained funding from the National Cancer Institute for nearly 25 years. I am also a proud member of, and until very recently served on the Board of Directors for, the American Association for Cancer Research (AACR). The AACR is the world's oldest and largest organization dedicated to advancing cancer research and its mission to prevent and cure cancer.

Thank you, Chairman Nelson and Ranking Member Collins, for convening this important hearing and recognizing that cancer research is critical to making and translating the discoveries needed to reduce the toll that cancer takes on the people and the economy of our Nation. It is my pleasure to be here today to talk to you about some of the outstanding scientific advancements we have made recently in the field of cancer research, as well as the challenges we face as we continue to advance the field for the benefit of the millions of Americans and their loved ones who face a cancer diagnosis.

Impact of aging and cancer on the state of Florida

One of the most defining socio-demographic changes ongoing in the United States is the dramatic increase in the number of older adults. Florida has nearly 20 million residents. Over 18% are older than 65 years, compared to 13.7% nationally. That is the highest percentage in the country and why some refer to Florida as "Heaven's Waiting Room." This age group is forecast to represent 24.1 percent of Florida's population in 2030. Most cancers are strongly associated with increased age. With the aging of our population, there will be a dramatic increase in the number of cancer diagnoses and mortalities, which some have referred to as a "cancer tsunami." Although Florida is the fourth most populous state, it is second in the nation in overall cancer incidence and mortality with over

17,000 residents diagnosed with cancer per year. Within the state, cancer is the leading cause of death. The growth rate of Florida is roughly 300,000 new residents per year, and many of those are coming to retire there. Over the next two decades, Florida's older population (age 60 and older) will account for most of Florida's population growth, representing 55.2 percent of the gains. These trends suggest we will soon rank first in the country in terms of cancer incidence and mortality. Thus, aging and cancer is a significant concern for the entire country, but especially acute for the state I live in.

The Moffitt Cancer Center and our efforts

Since its inception in 1986, the Moffitt Cancer Center has had a single mission: to contribute to the prevention and cure of cancer. Our 206-bed cancer hospital and outpatient clinics are among the busiest in the U.S., treating more than 50,000 cancer patients per year from all 50 states and 78 countries around the world. We have been ranked on U.S. News and World Reports "America's Best Hospitals" list since 1999. In addition, Moffitt is a major economic engine that employs 4,300 people and generates more than $1.7 billion in direct economic output.

In addition to taking care of cancer patients, we have a thriving research enterprise, representing about 20% of the workforce and supported by more than $50 million in research grants and contracts, the vast majority of which is supported by the National Cancer Institute (NCI), the largest Institute at the National Institutes of Health (NIH). In fact, Moffitt is the only NCI-designated comprehensive cancer center based in Florida, and one of only 41 in the country. The comprehensive cancer center designation by the NCI is awarded through a competitive peer-review process and based on our research in the population, in the laboratory, and at the bedside. The NCI-designated Cancer Centers are a major source of discovery of the nature of cancer and of the development of more effective approaches to cancer prevention, diagnosis, and therapy. In addition, they also deliver medical advances to patients and their families, educate health-care professionals and the public, and reach out to underserved populations. Many view the NCI Centers as the nexus for the creation of therapies that will lead to the cure of cancer. From the window of my office, I see hundreds of cars lining up each day, filled with patients, family and friends who are coming to us for one reason – hope. Their hope often lies in the opportunity to participate in clinical trials of novel interventions. At our institution alone that means access to more than 400 clinical trials testing therapies that lead to new standards of care, including, very recently, groundbreaking success in the treatment of melanoma.

But because of federal budget cuts and a shrinking pool of money at the NCI and NIH, funding for this critical program, as well as many other essential programs at the NCI, has been declining for the past decade when factoring in the rate of biomedical inflation. These budget cuts could not be coming at a worse time - a

time of unprecedented opportunity to translate the science that exists today into improved care for cancer patients.

How does Moffitt meet the needs of elderly cancer patients?

The Senior Adult Oncology Program at Moffitt Cancer Center is the first comprehensive geriatric oncology program created in the United States. This program includes a multidisciplinary team of experts with the longest worldwide experience in the treatment of older cancer patients. Great strides have been made, based on rigorous and empirical clinical research, in learning how to tailor cancer treatments to each patient based on their biological age, rather than their chronological age. This has led to important advancements that help older people with cancer, including teaching us how to factor in the high prevalence of chronic conditions and other health problems experienced by elderly patients when they come to us, which are independent of their cancer prognosis.

For example, Moffitt's Senior Adult Oncology group has developed the Comprehensive Geriatric Assessment, which is now being used at academic medical centers throughout the world. This is a tool to evaluate an individual's tolerance to chemotherapy and other cancer treatments. With it, we are able to modify treatments to produce better results while minimizing harmful side effects.

Instead of "one size fits all" cancer treatments, we can choose less aggressive approaches for less healthy patients. On the flip side, we can also identify patients in their seventies who are as fit as people twenty years younger and can do just as well as younger people with aggressive cancer therapy.

An NIH-funded clinical trial currently underway at Moffitt bears this out, by showing that many patients in their seventies, long thought to be too old to receive blood and bone marrow transplants, can actually qualify for this lifesaving therapy if they meet certain criteria.

Progress and challenges

We find ourselves at a propitious moment in our country's long struggle to cure and prevent cancer. We are in an incredibly exciting and promising time in science and cancer research, and the good news is that we have made significant progress. The cancer death rate has declined by 1 percent each year for the past two decades, resulting in more than 1 million lives saved. The number of Americans living with, through or beyond a cancer diagnosis has almost tripled since the 1970s.

According to the most recent AACR *Cancer Progress Report*, 13 new drugs to treat a variety of cancers; six new uses for previously approved cancer drugs; and three new imaging technologies have been approved in just the past 18 months. Moreover, there are now 41 FDA-approved therapies that target specific

molecules involved in cancer, compared with 17 five years ago, and just five 10 years ago.

These advances in cancer research and cancer care are the direct result of the past investments our country has made in the National Institutes of Health (NIH) and the National Cancer Institute (NCI). These investments have accelerated the pace of discovery and the development of new and better ways to prevent, detect, diagnose, and treat cancer in all age groups.

A significant milestone for cancer research -- which NCI funding made possible -- was the discovery that cancer develops as a result of alterations in the genetic material of cells. Research in genomics has propelled technological innovations that are making it possible to efficiently read every known component of the DNA from an individual's cancer. These discoveries are changing the way doctors view cancers, categorizing them increasingly by the genetic changes that drive them and less by where they originate—in the breast, brain, lung, or liver, for example. In fact, by continuing to invest in how different cancers share molecular features and applying the knowledge learned across many different types of cancers, we are optimistic that this will most notably improve the treatments for patients whose cancers have 5-year survival rates at less than 50 percent, such as in the case of small-cell lung cancer, a disease whose five-year survival rate is less than 15 percent.

At Moffitt we have an ambitious research protocol, called Total Cancer Care, that seeks to consent every cancer patient who comes through the door to provide access to their medical record, permit us to analyze their tumor to understand the molecular changes that have accumulated, and to follow them for the rest of their journey with cancer. We had to create a health research information platform to integrate the data, as nothing like it had ever been built. We even had to create new departments to deal with data quality, data governance, and educate the clinical, research, and administrative workforce on the myriad of potential applications. We have enrolled more than 100,000 patients in this unique partnership.

One of the ways that Moffitt's Total Cancer Care database accelerates the improvement of cancer care is that it allows us to identify genetic factors which cause some patients to respond differently to treatment than other patients. Knowing these factors can help us select the treatment best suited to each patient and their disease without the trial and error process that doctors have had to use in the past. The data are used by our researchers to identify targets for drug development and by clinical investigators to test new therapies on the subset of patients that would be predicted to benefit. This precision medicine approach is expected to further improve outcomes, reduce side effects, and eliminate the use of treatments that can be predicted to not work for that patient.

This approach is especially useful when treating cancer in older adults, who have a higher prevalence of chronic conditions unrelated to the cancer diagnosis. Standard treatment options, including chemotherapy, insufficiently account for the disease burden commonly attributed to these patients. Being able to recognize and manage these issues associated with the geriatric community has a dramatic effect on the way we treat older people with cancer.

The Total Cancer Care study was initiated with investment from the pharmaceutical industry and state and local government. This public-private partnership exemplifies how federal funds from the NIH and NCI can be leveraged at the state and local levels, as well as with the private sector.

Therefore, as a researcher and a cancer center director, it is extremely frustrating that at a time of increased scientific possibility and discovery, we are experiencing decreases in funding. Indeed, our ability to continue to deliver the promise of science to our patients is in great jeopardy. Despite the additional funds provided in the current fiscal year, the NIH and NCI budgets remain below fiscal year 2012 levels and below levels prior to sequestration. In addition, the NIH has lost more than 22 percent of its budget after inflation over the past decade, which is significantly impacting our Nation's ability to sustain the scientific momentum that has contributed so greatly to the successes in cancer prevention, detection, diagnosis and treatment.

These cuts not only have a negative impact on current biomedical researchers, but also they will impact future generations of scientific researchers and ultimately our citizens who are counting on us for a cure. For the first time in my career we are seeing fewer grants submitted to the NIH, especially by first-time investigators. The competition for the scarce grant dollars are driving many out of the field, often after years of graduate and post-graduate education, before they even get in the game. As I look around at my peers, I see all us getting older and starting to think about the next phases of our lives. I can't help but wonder who is going to be left to carry on the great tradition of biomedical research in this country. The loss of this generation not only affects our near term potential to create the knowledge that leads to new preventive and therapeutic strategies, but ultimately, to longer-term negative consequences for our nation's global competitiveness.

The future can be bright

There has been progress against cancer. The opportunity to make a significant impact based on recent discoveries and amazing technological advances is at our fingertips. The need is great: more than 1.6 million Americans are expected to receive a cancer diagnosis this year, and more than 580,000 Americans will lose their lives in 2014 to this devastating disease. That equates to one person losing their battle with cancer every minute of every day. Cancer is clearly not only a costly disease in terms of lives lost, but also in terms of dollars spent.

Annually, cancer costs our country more than $215 billion in direct and indirect costs.

The federal government has an irreplaceable role in supporting medical research. No other public, corporate, or charitable entity is willing or able to provide the broad and sustained funding for the cutting edge research necessary to yield new innovations and technologies for the cancer care of the future. It is because of past and current funding received from the NIH that cancer centers like Moffitt can attract and maximize funds from state and local governments, as well as from foundations and other private sources – not to mention thousands of community contributions, large and small.

Without increased funding now, the spectacular advancements we have witnessed in the past will not be there in the future. Without increased funding, the younger generations of academic researchers will be forced to leave science for other fields. With the loss of researchers we risk delaying breakthroughs and discoveries, which could translate to increased morbidities and mortalities associated with cancer. As a country we must set priorities at this difficult time in our history—and the federal government can do no better with its money than continue to invest in medical research.

Scientific momentum has ushered in the arrival of a new era in which we can develop even more effective interventions and save more lives. So this is not a time for the NIH and NCI budgets to be in retreat. Cancer researchers at Moffitt and other cancer centers across the country are on the verge of many other breakthroughs that will benefit cancer patients, but our ability to realize this potential will depend in large part on the level of NIH and NCI funding that will be available for cancer research in the future.

For this to occur we will require an unwavering and bipartisan commitment from Congress and the Administration to invest in our country's remarkably productive medical research enterprise. With robust support, research can help us to accomplish the ultimate goal once articulated by the late Dr. Ernst Wynder -"to help people die young, as late in life as possible".

Thank you, and I look forward to answering any of your questions.

Statement of Mary Dempsey, Assistant Director and Co-Founder of the Patrick Dempsey Center for Cancer Hope & Healing

Thank you for inviting me to speak today. My name is Mary Dempsey-I am the Assistant Director and Co-Founder of the Patrick Dempsey Center for Cancer Hope & Healing. We are located in Lewiston, Maine.

My Mother, Amanda Dempsey, was diagnosed with Ovarian Granulose Tumor Cell Cancer on August 19, 1997. Over the course of seventeen years, my mother had a total of twelve recurrences. As my family navigated the first two recurrences, we realized the necessity for emotional and community support that patients and families need when going through this unknown experience. My brother, Patrick, assisted in the partnership with Central Maine Medical Center where we joined with an experienced Oncology Social Worker to develop the concept for a local cancer support center that was caring, warm, and provided opportunities for healing, and would be accessible to anyone impacted by Cancer.

I understand first hand that a cancer diagnosis feels like a death sentence. There have been tremendous advances in the field of oncology that now allow more people to live with this disease as a Chronic illness. My mom lived this experience, and I shared it with her as her primary caregiver. In this role, I experienced first-hand the impact Cancer had on every part of my life. For me, it really became a full time job; navigating resources, understanding the medical world, and coping with the profound changes in our lives.

While physicians and other oncology professionals provide great medical care to treat the disease, cancer patients and their families need additional support to treat the person and those who surround them. Cancer affects the whole person and the whole family.

At the Dempsey Center, we understand that when resources are strained the first thing that is often sacrificed is the emotional care needed to endure ourselves through tough times. As a result, the Dempsey Center offers an array of services including professional cancer support, education, and integrative medicine services for all ages, free of charge and regardless of where the patient received their treatment. Much like other Cancer centers we also provide many opportunities for people to give back such as creating comfort items, donating time and skills to help the Dempsey Center operate, and of course volunteering at our annual Dempsey Challenge.

Patrick has helped sustain the Center financially through not only his own generous contributions but his vision of the Dempsey Challenge, our largest annual fundraising event. The Challenge is an event, not a race, where patients, families and communities from all around the world come together to support this cause, which is common in many households. At this event participants can walk, run or cycle at their own pace. Like the Dempsey Center itself, the event has more depth than what it may appear. It is a community celebration, and more importantly a recognition that we are in this together. Every year since 2009, my mother, has lead the Amgen Breakaway from Cancer Survivor Walk alongside our family and the many cancer survivors, who come together to take their journey one step at a time. This year she will be there in Spirit, like so many that have come before her and so many that will come after her, and we will continue working towards our mission of raising awareness, encouraging hope, and offering healing through our collective presence.

In closing, Mom passed away March 24th this year. She did not lose the battle; she defied the odds and lived each day to her best ability. After all, this is what living with cancer is about. Not letting a disease prevent you from life; she beat-up Cancer. The mission of the Center will forever be intact through her legacy and our commitment to help anyone impacted by Cancer travel their journey as gently as possible. We will continue to be a beacon of light in the thickness of the fog.

Thank you.

Statement of Chip Kennett, Advocate and Cancer Survivor

Chairman Nelson, Ranking Member Collins, Members of the Committee and staff, I want to thank you for holding this hearing on a subject that has most likely touched the lives of everyone in this room, but as I have learned over the past 18 months, you don't have a complete understanding of everything that is involved with a cancer diagnosis and prognosis until you receive one. I am grateful the Committee is taking the time to explore this issue further, and I hope I am able to add some value to the Committee's efforts.

I want to start off by saying that I hate all forms of cancer. The Committee has asked me to testify about my personal experience, so I will primarily be focusing on lung cancer, but I strongly support the funding for and the eradication of every single type of cancer.

My journey to testifying at this hearing began in the fall of 2012. I was a 31 year-old father of a wonderful two year-old boy named Joe and my wife, Sheila, was 35 weeks pregnant with our baby girl, Crosby. I was by all accounts "healthy"--there was just that nagging, blurry spot in my right eye that showed up and wouldn't go away. Since it had been a couple of years since my last eye exam, I scheduled an appointment with my eye doctor who suspected the blurriness was from a detached retina. After seeing several eye specialists and undergoing a series of tests, I was told I potentially had melanoma of the eye, but it's extremely rare for cancer to originate in an eye. Tumors in the eye are most likely a metastasis, so it was recommended I schedule an MRI and PET scan through my general practitioner.

That series of events led my wife and me back to the same doctor's office, where just a few months earlier I had passed my annual physical with flying colors, where we were told the results of the PET scan were "all lit up" and that I had cancer "everywhere"— in both of my lungs, liver, lymph nodes and bones, plus my right eye. A week later, a biopsy revealed I had non-small cell lung cancer. In just three and a half weeks, I went from seeing a blurry spot to being told I had a year, maybe two, to live, and that I was being treated for longevity and quality of life.

My wife and I were anxious to start treating the disease as soon as possible, but we were advised to wait for even further testing to be completed because within non-small cell lung cancer, genetic cell mutations can occur and selecting the proper method of treatment was essential. Further testing revealed I had a genetic cell mutation affecting less than five percent of adenocarcinoma patients called ALK translocation. On my son's third birthday, I learned I was ALK+. It's all relative these days, but we were ecstatic with this news, because in previous consultations with oncologists, we knew there was an approved and targeted "smart" drug that specifically treated this genetic cell mutation.

Despite living through it, it is still difficult for me to put into words for the Committee what that experience is like. I don't mean it makes me emotional to recall what happened during those first couple of weeks--what I mean is there are really no words to describe what it feels like to be told you have an incurable disease that will kill you. I hope and pray no one within the sound of my voice has to experience what I am failing to describe, but unfortunately, the odds are many will.

One in every 14 people will receive a lung cancer diagnosis and due to the lack of a reliable form of early detection when the disease is more treatable, lung cancer is the most lethal form of cancer regardless of gender or ethnicity. It kills more people each year than breast, colorectal, pancreatic, and prostate cancers combined. According to the National Cancer Institute, approximately 160,000 people will lose their lives to lung cancer this year. That is the equivalent of a jumbo jet falling out of the sky every single day for an entire year. The five year survival rate for lung cancer patients is only 16 percent. For stage four patients like me, the chances I live more than five years is only one percent. That means I have a one percent chance of watching either of my kids enter the first grade, much less watch them graduate from high school, walk my daughter down the aisle, grow old with my wife or hold a grandchild in my lap.

Lung cancer kills almost twice as many women as breast cancer and almost three times as many men as prostate cancer, yet the funding lung cancer receives pales in comparison in large part due to the stigma that lung cancer is self-induced as a result of smoking. This is a stigma that needs to end. I believe smoking is a terrible addiction and have never smoked myself, but lung cancer is not just a smoker's disease. We must change this perception of lung cancer in order to make more progress in combating this country's second leading cause of death. The recently passed Recalcitrant Cancer Act directing the National Cancer Institute to focus more resources on cancers with lower survival rates is an encouraging step in the right direction.

I have included a number of statistics in my testimony today, but I don't consider myself to be a statistic. I never have. In fact, my age and form of lung cancer makes me an outlier, but statistics are driven by facts and the facts are more funding is needed for lung cancer research. Research saves lives, and I am a living example of that. The drugs that have kept me alive for the past 18 months were not available just seven years ago.

The first drug I was on, Xalkori, or Crizotinib, is a "smart" oral chemo which specifically targets the ALK translocation. It proved to have immediate and dramatic results. Within a week of being on Xalkori, I had regained my energy, my vision was almost clear, I was back to work and most importantly, was present at the birth of our daughter. Within two weeks, I was exercising again. Unfortunately, after two short months, the efficacy of Xalkori played out just as dramatically, and I wound up on the operating table to have cancerous fluids drained from around my heart and both of my lungs.

Thanks to my amazing team of doctors, I was soon enrolled in a clinical trial for another oral chemotherapy, a second generation ALK inhibitor, LDK378, at Fox Chase Cancer Center in Philadelphia, PA. The average response rate to LDK is seven and half months which is approximately how long I was in the trial before I started having major complications and progression of disease. During those seven and a half months, I watched my son turn four and my daughter turn one, and my wife and I spent a week driving the Pacific Coast Highway which is

something we had always wanted to do together. LDK378, now known as Zykadia, is the same drug that received the FDA's breakthrough therapy designation last week and managed to do so within three years of the first patient being enrolled in the trial; I was one of 163 participating patients.

Unfortunately, earlier this year, the progression of disease was significant enough that in January, my oncologists moved me to straight to a non-targeted, traditional intravenous chemotherapy at Johns Hopkins which essentially poisons both healthy and unhealthy cells resulting in what can be severe and traditional side effects most commonly associated with chemotherapy. After two rounds of chemotherapy, scans revealed further progression of disease, so eight weeks ago, I began my second clinical trial, an immunotherapy trial at Johns Hopkins under the direction of my amazing oncologist, Dr. Julie Brahmer. In short, the idea of immunotherapy is to trick your body's own healthy cells into attacking the unhealthy cells. Side effects have been minimal, I have been feeling really well, and I have my first set of scans on this trial at Johns Hopkins tomorrow morning.

If you are keeping track, 18 months post-diagnosis, I am now on my fourth treatment. These targeted treatments, such as Zykadia, have allowed me to live a relatively normal and productive life. Thanks to these medical breakthroughs, I have been able to experience many quality filled days. We have enjoyed spending holidays with friends and family. I have been able to continue working full time. As a family, we have sat down at the dinner table together, have attended innumerable swim lessons, soccer and tee ball practices for my son on Saturday mornings, and have sat in a church pew together on Sundaymornings. In other words, we have stayed busy--busy LIVING with cancer.

As a late stage cancer patient, I am fully aware I am "kicking the can" so to speak. Luckily, I have honed my procrastination skills over the years, and with the right combination of science, prayer and the love and support we receive from our friends, family and even total strangers affectionately known as "Team Kennett," we fully intend to keep on kicking that can from trial to trial until one day, we can all celebrate a cure for cancer.

Again, I thank the Committee for holding this hearing and stand ready to answer any questions you may have.

Questions for the Record

Special Committee on Aging
United States Senate

Harold Varmus, M.D.
Director, National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services
May 7, 2014

Questions for the Record

Senator Bob Corker

1) **During the hearing you stated that roughly 13% of grant applications are currently funded at the National Cancer Institute. This is a decline from 2008 when 20.6% of applicants were funded. Please discuss NCI's strategy when funding applications, specifically whether the Institute sees a scientific advantage in funding either a larger number of smaller projects or funding a smaller number of larger projects. Is there any evidence that shows either strategy leads to greater scientific advancements?**

Response: As you point out, the success rate for applicants for Research Project Grants (RPGs) has declined over time. In 2013, the most recently reported year, the NCI awarded 1,095 competing RPGs, resulting in a final success rate of 14 percent.[1]

The declining rates are due to a combination of factors: an increased number of applicants, reductions in dollars appropriated to the NCI (and NIH overall) in the past few years, and loss of our "buying power" due to inflation during the past decade. Over the past few years, despite declines in our appropriated dollars, we have sustained the number of new and competitively renewed RPGs by adjusting other parts of the NCI budget and protecting the budgets assigned to investigator-initiated research.

We make decisions about which grants to fund based on a combination of considerations that include the intrinsic quality of the proposals, as judged largely by external peer reviewers, and the importance of the research topic, as evaluated by program staff and NCI's scientific leadership. We also try to ensure that we are providing sufficient funds to allow investigators to carry out the intended work; as a result there is a broad mixture of awards categorized by size and funding mechanism. We believe that grants of all sizes have merit and purpose, but we also acknowledge that the increasing costs of medical research, combined with a relatively stable average size of RPGs, may slow the conduct of the proposed work.

2) **As Senator Collins alluded to in the final minutes of the hearing, medical research in the United States is currently conducted at several agencies, including the National Institutes of Health, the Centers for Disease Control and the Department of Defense.**

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[1] https://gsspubssl.nci.nih.gov/blog/articles?funding_patterns/2013

Do you believe that conducting cancer research at multiple agencies leads to faster advances rather than a model that would house medical research under the umbrella of a single agency? Is there communication and collaboration among these agencies to reduce duplication?

Please discuss the possible benefits and drawbacks to placing all medical research under the auspices of the National Institutes of Health.

Response: There are good reasons for and benefits from the conduct of medical research by multiple Government agencies, in part because the missions of the agencies differ, the scope and disciplinary nature of the research may differ, and in times of fiscal constraint the aggregated resources devoted to medical research may help to meet important goals. Medical research, including cancer research, is of course supported by many entities other than Federal Government agencies---industry, philanthropic groups, and academic institutions in the United States and many other nations---and the scientific community uses a variety of means---national and international meetings, the scientific literature, and informal contacts---to stay abreast of developments funded by these various sources and minimize redundancy.

Special efforts are made to increase coordination among Federal Government agencies involved in cancer control. Sometimes these are based on differences in mission. For example, the NCI's cancer control mission emphasizes research on the means of controlling the use of tobacco, whereas CDC primarily funds state tobacco control programs to implement cessation interventions that have been shown to be effective. In this sense, the agencies' activities complement each other, as NIH research informs the evidence base for CDC's tobacco cessation interventions.

In other situations, the balance is facilitated by exchange of information. For example, Dr. Jonathan Woodson, Assistant Secretary of Defense for Health Affairs at the Pentagon, serves as an ex-officio member of the NCI National Cancer Advisory Board. Dr. William Dahut, the Clinical Director at NCI's Center for Cancer Research, sits on the FY 2014 Integration Panel, an external advisory board, for the Department of Defense (DoD) Prostate Cancer Research Program, and NCI's Dr. Eva Szabo serves on the FY 2014 Integration Panel for the DoD Lung Cancer Research Program.

Coordination also occurs through interagency working groups, such as the Interagency Breast Cancer and Environmental Research Coordinating Committee, which includes representatives from the NCI, NIH's National Institute on Environmental Health Sciences and Office of Research on Women's Health, the CDC, the DoD Congressionally Directed Medical Research Program, and the Environmental Protection Agency.

Senator Joe Manchin III

3) **The Mary Babb Randolph Cancer Center, in Morgantown, West Virginia, is one of the best cancer centers in the country. Just this week, my staff met with a physician from the center who is involved in clinical trials and passed along some alarming information to us. I was told that in 2009 there were over 30,000 patients enrolled in cancer clinical trials, but in 2014 we expect less than 20,000 patients to be enrolled in cancer clinical trials due to decreased funding.**

   With a 30% reduction in just 5 years, how will this impact our ability to find cures and treatments for cancer patients?

   What about the scenario when a clinical trial has already been opened but has not yet finished accruing patients?

   Might these cuts cause some promising trials to close prematurely?

   I realize that Congress has to allocate the money, but do you think more funding needed for oncology clinical trials?

Response: Advances in cancer research have fundamentally changed our approach to cancer treatment and created the need for a more efficient and streamlined clinical trials system that is able to respond more rapidly to scientific opportunities. In March 2014, following many years of consultation with stakeholders and advocates, the NCI completed the transformation of its longstanding Cooperative Group program into the new National Clinical Trials Network (NCTN). The process was guided, in part, by recommendations in a 2010 Institutes of Medicine (IOM) report. NCI's prior clinical trials system, the Cooperative Group Program, produced many important advances over more than 50 years. Extensive reviews by expert committees concluded, however, that to more effectively and efficiently complete trials and to take optimal advantage of rapid improvements in technology, the system had to be restructured.

Some of today's clinical trials are designed differently, and require fewer participants to achieve the goals of the trial. Often, trials now require screening large numbers of patients to find those whose tumors exhibit the appropriate molecular profile for a specific targeted treatment. While the interventional trials may be smaller, the number of patients to be screened to find appropriate participants often requires a much larger number through a national outreach. If a specific molecular alteration can be detected in a patient's tumor, the trial can detect larger differences in clinical benefit (such as how long patients live overall or live without tumor progression) between the intervention and control groups and in a shorter period of time. More precision in patient selection will permit study designs that can aim for larger therapeutic effects and thereby further decrease the size of trials.

The new system provides for an annual enrollment of about 17,000 patients on interventional trials, a 15 percent reduction compared with about 21,000 enrolled patients in recent years. This reduction is anticipated to occur gradually, over 2 to 3 years. To this end, NCI has reserved funds

to distribute to the NCTN groups later in the current fiscal year (FY 2014) to accommodate an enrollment of about 21,000 patients. The highest annual accrual in the former Cooperative Group system occurred about five years ago and was about 27,000 patients, due primarily to a single very large trial. As mentioned above, in recent years, the accrual has trended downwards. Also, to be fully accurate, the 30,000 accrual figure cited was not a result of Group trials only b included other trial networks that NCI supports, especially those for early phase trials like the Adult and Pediatric Brain Tumor Consortia and the early phase-1 and -2 trial networks. These networks continue to enroll about 3,000 additional patients annually.

Every clinical trial proposed within the NCTN is rigorously evaluated by the disease-specific Steering Committees (comprised of extramural researchers) in terms of its likely impact on changing oncology practice within that disease area and really helping patients. The goal is to fund only those trials with a substantial likelihood of advancing the standard of care and changing practice.

Promising trials will not be closed prematurely. NCI has committed to working with Cooperative Group Chairs to ensure that no active trial that is meeting its accrual goals will be closed as part of the transformation to the NCTN, and NCI staff are working with the Group Chairs to make sure that trials are completed. With its state-of-the-art clinical trials infrastructure, the NCTN is poised to implement and complete trials far more rapidly than in the past. For physicians and their patients, a menu of important trials will be widely available throughout the country, in large cities and small communities alike. The NCTN will be capable of offering access to the best approaches available for many common and, increasingly, even rar cancers.

The NCI Community Oncology Research Program (NCORP), another component of NCI's clinical trials programs, was formed by restructuring three community oncology programs (the Community Clinical Oncology Program, the Minority-Based Clinical Oncology Programs, and the Community Cancer Centers Program) into a single entity. NCI has planned for a responsible transition into the new structure to ensure the continuity of patient care and existing studies. NCORP will design and conduct trials to improve cancer prevention, cancer control, screening for early cancers, and post-treatment surveillance; it will also study delivery of cancer care and perform comparative effectiveness research. NCORP will also emphasize the importance of including minority and other underserved patient populations in clinical research, posing research questions that address health disparities in many aspects of cancer control and cancer care. In addition, NCORP will facilitate access to treatment and imaging trials conducted by the NCTN.

NCI has maintained its commitment to a strong clinical trial enterprise and has invested additional funds to support a variety of centralized functions for the Cooperative Groups such as tumor banking, a central Institutional Review Board, and a cancer trial support unit for administrative functions. Certainly, there will always be more research questions and opportunities than resources to pursue them all, but NCI is focusing its attention on its highest priority needs within the funds appropriated to it.

Statements for the Record

Statement of United States Senator Robert P. Casey, Jr.
Special Committee on Aging Hearing on
The Fight Against Cancer: Challenges, Progress, and Promise
May 7, 2014

Chairman Nelson and Ranking Member Collins, thank you for holding today's hearing to provide us with a progress report on the advances in cancer research as well as the experiences of cancer patients and families. An estimated 1.66 million Americans were diagnosed with cancer in 2013, and over 79,000 of these diagnosed individuals lived in Pennsylvania. Considering the number of families who are touched by this disease, I feel that this is a very timely hearing.

Great strides have been made in research on the identification, treatment, and curing of cancer; however, there are still almost 1,600 people who die daily from cancer – or over 585,000 in 2013 alone. Almost 29,000 Pennsylvanians died due to cancer last year. When the National Cancer Institute (NCI) was founded in the 1970s, about 50 percent of cancer survivors lived at least 5 years after their diagnosis. Today, 2/3 of cancer survivors live at least 5 years after their diagnosis. Can we continue to improve on these statistics?

New drug treatments and imaging technologies are being developed, tested, and approved at an increasing rate, and much of this progress is made possible by support of NCI funded research. In Fiscal Year 2014, NCI supported almost 2,200 research awards totaling over $851 million nationally. Institutions in Pennsylvania received 157 awards from NCI in FY14, totaling over $103 million. For FY15, Senator Burr and I led an appropriations letter signed by 55 of our Senate colleagues to request that the Labor-Health and Human Services-Education appropriation bill include a strong commitment to funding for the National Institutes of Health (NIH). Investment in the NIH are our best hope for treating and curing diseases such as cancer.

Challenges still exist as we fight cancer. I understand that cancer is more common in older adults, but older cancer patients are often left out of cancer clinical trials for fear their age and additional chronic conditions will skew the research results. This is a loss. With the aging of our population we are at a critical point where we need research and knowledge to identify and treat cancer for a growing population who is likely to have chronic conditions.

With the number of older adults expected to double by 2050, research such as that supported by the NCI is vital. The challenges we face with an aging population draws particular attention to the unique considerations of cancer and aging. I encourage the efforts of the NIH, and the NCI specifically, to continue conducting the research essential to win the fight against cancer.

I again would like to thank the Chairman and Ranking Member for calling this hearing. I look forward to hearing the testimony and working with my colleagues in the fight against cancer.

Clifford A. Hudis, MD, FACP

President
American Society of Clinical Oncology

Testimony for the Record prepared for:
United States Senate Special Aging Committee

The Fight Against Cancer: Challenges, Progress, and Promise

May 7, 2014

The American Society of Clinical Oncology (ASCO), the world's leading professional organization representing nearly 35,000 physicians and other professionals who treat people with cancer, appreciates this opportunity to provide testimony on the importance of cancer research for older Americans. ASCO further would like to thank the Committee for convening this important hearing.

Cancer's Growing Footprint and the Aging American Population

The leading overall risk factor for cancer is aging. With progress in many areas of health care more Americans can live longer potentially increasing the burden of cancer. Indeed, the aging population presents significant new challenges in the healthcare system, especially in cancer. According to ASCO's *State of Cancer Care in America* report (http://www.asco.org/practice-research/cancer-care-america) released earlier this year, even as the outcomes improve for individuals, cancer will surpass heart disease as the leading cause of death in the United States (US) over the next 16 years. Hence, while cancer deaths in the US are declining for all populations, the number of new cancer cases is expected to increase nearly 45 percent by 2030, from 1.6 million cases to 2.3 million cases annually. Most of these cases will be in older Americans.

Ensuring Cancer Research for Older Americans

While we have made great strides in cancer treatment, the potential for even greater gains is real and now is not the time to cut back. As cancer impacts more and more Americans we now have more cancer survivors alive today than at any point in our history and understand more about the diseases that make up cancer than ever before. This is true largely because of federal investment in cancer research over the past decades but we will not be able to leverage our gains harness new opportunities that build on our success without further investment. Adjusting for inflation, funding for the National Institutes of Health (NIH) is down 23 percent

since 2003. In addition, the National Cancer Institute (NCI) has become a smaller share of NIH's total budget than previously. If the NCI was funded at the same percentage of overall NIH spending that it was in 2003, it would mean an additional $350 million for cancer research.

Although older adults comprise the majority of cancer patients and survivors, older adults are under-represented in research. When older adults are included in clinical trials they are not representative of the typical older adult - they are younger and healthier with fewer concurrent illnesses or conditions. In the geriatric usage sections of the drug package inserts for 24 drugs approved for cancer treatment between 2007 and 2010, only 33 percent of the participants were age 65 and older although 59 percent of the cancer population is age 65 and older. A systematic review of 345 phase 3 trials conducted by 5 NCI Cooperative Groups found that 57 percent of trials had no stratification by age and only 12 percent of studies had stratification of age greater than 65 years.

The lack of research specifically focused on older adults is problematic because it makes it difficult to generalize research results to the specific patient when making treatment decisions. ASCO is taking under consideration many of the recommendations in the Institute of Medicine (IOM)'s 2013 report *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis.* The IOM makes several recommendations to improve our evidence base in older adults. ASCO's Cancer Research Committee is forming a working group to examine the IOM recommendations and identify ways that we can advance involvement of the elderly in cancer research. Part of the solution may lie in broadening the type of research we conduct with new cancer therapies, particularly in the post-approval setting. It is critical that we continue to capture more data about cancer patients' experiences as we use drugs in the broader population. In addition, our Cancer Research Committee is developing recommendations regarding eligibility criteria with the hope of limiting those criteria that routinely exclude people from participation in clinical trials. This is particularly important with the increase of molecularly targeted agents. We hope that greater understanding of the molecular basis of cancer, the availability of agents with greater efficacy and fewer side effects, and improved ability to capture electronic data in a post-approval setting will all increase our ability to deliver the most effective use of therapies to all cancer patients with evidence-based allowances for age and other factors.

Ensuring Access to Cancer Care for Older Americans

In addition to the need for greater research investment, ASCO is greatly concerned about a growing crisis in the US cancer care delivery system that especially impacts older Americans. As the demand for care grows with an aging population, workforce shortages, payment cuts, and consolidation of oncology practices are causing potential access limitations with regard to cancer care specifically.

The IOM report states that meeting the needs of the aging population will have to be an integral part of improving the quality of cancer care. As we have noted the majority of cancer

diagnoses and cancer deaths are in older adults, and the majority of cancer survivors are in this age range. In addition, there are many unique considerations to understanding the prognoses of older adults with cancer and formulating their care plans (e.g., altered physiology, functional and cognitive impairment, multiple coexisting morbidities, increased side effects of treatment, distinct goals of care, and the increased need for social support).

The data in ASCO's *State of Cancer Care in America* report shows supports the observations of the IOM and shows that the demand for cancer prevention, screening and treatment services is growing rapidly, with much of the demand coming from older Americans. As the number of cancer cases grows, so will the number of cancer survivors, now at 13.7 million. Many of these individuals will require significant, ongoing care.

Soaring costs have created an urgent need to improve the value of patient care. While costs are rising throughout the healthcare system, the trend is especially pronounced in cancer care—annual costs are projected to rise from $104 billion in 2006 to more than $173 billion in 2020. This increase is a result of many factors, including the cost of many new cancer therapies. Access to high-quality cancer care will be sustained and expanded only if we address these rising costs, including the use of unnecessary or ineffective tests and treatments. Identifying higher value care will require appropriate additional resources.

After reviewing the current need for cancer care in America, ASCO's *State of Cancer Care* report examines future challenges to the US cancer care system, offering recommendations in three critical areas. The first is the oncology workforce. ASCO regularly monitors the size, distribution and diversity of the US oncology workforce to identify trends that could affect patient access. ASCO estimates that, by 2025, demand for oncology services will grow by 42 percent or more, while the supply of oncologists will grow by only 28 percent. These trends predict that there could be a shortage of more than 1,487 oncologists by 2025. The demand for services that accompany the tremendous growth in the number of Americans over the age of 65 will be made more acute by the aging of the oncology workforce and large numbers of anticipated retirements as well as other factors that reduce the effective number of practitioners and practices.

High quality oncology care relies on a variety of health care professionals bringing a wealth of expertise to the patient throughout the continuum of care. This includes collaboration across settings – primary care, surgery, radiation oncology, medical oncology, palliative care, and hospice – as relevant to the experience of the person with cancer. It also includes collaboration among health care providers within each setting. The team-based model has been essential in oncology since the beginning of the specialty. Examining innovative ways to organize are delivery will be an important component of how we deliver care more efficiently to the growing number of cancer patients. This should involve promoting access to trained professionals within the capacity of their skills, training, and expertise to deliver patient-centered care. A care setting that promotes the team model of care is correlated with professional and patient satisfaction, which also helps foster a culture that protects accountability, focuses on patient

safety, ensures quality care, and provides useful information to consumers. In addition, we should also be examining how we can make better use of specialized knowledge in a virtual capacity. Even if we are able to add more health care providers, there will continue to be parts of the country where access to health care is challenged by geographic factors. Expanding our ability to use telemedicine is one way we may be able to facilitate specialized care in a timely and patient-centered way.

This second area of concern is in oncology practice. ASCO's report highlights findings from ASCO's second annual census of US oncology practices, conducted in 2013, along with related data from other sources and found that practice sizes are increasing and practices face growing financial instability. The greatest threat is faced by small community-based practices. Nearly two-thirds of small practices (63 percent of those with 1-2 physicians) reported that they were likely to merge, sell or close operations in the next year.

To sustain oncology practices' ability to meet patient needs in every community, ASCO recommends that payers should align payment systems with the goal of delivering high-value, patient-centered care, and provide funding and support to help struggling practices make the transition to value-driven payment models. ASCO recommends testing a range of promising cancer care delivery models that address the unique challenges of treating the disease. Specifically, policymakers should launch demonstration projects through the Innovation Center within the Centers for Medicare & Medicaid Services or other appropriate avenues. Further, we must reduce risks and unpredictability in federal payment systems. This includes repealing the flawed Sustainable Growth Rate (SGR) formula and reversing Medicare cuts caused by sequestration, along with other financial pressures that are disproportionately harming small community practices.

Finally ASCO is working to ensure high quality cancer care for all Americans, including seniors. Although the US cancer care system is arguably the world's best, the quality of care remains inconsistent, contributing to disparities in outcomes and unnecessary costs. Data from ASCO's Quality Oncology Practice Initiative (QOPI®), in which more than 850 oncology practices have participated, offer compelling evidence of improvement on several measures, related to both cancer-specific treatment and broader measures such as high-quality end-of-life care.

Both Medicare and private insurers should continue working with physicians to pilot test new payment or care delivery approaches that reward high quality care. These range from clinical pathways to patient-centered medical homes, which promote aggressive disease management, care coordination and strong patient/physician communication.

The adoption of health information technology is already transforming many aspects of cancer care, but more dramatic change is on the horizon. Within years, big data initiatives such as ASCO's CancerLinQ™ and the collaboration between IBM's Watson and Memorial Sloan Kettering Cancer Center will unlock and analyze data from large numbers of patients—and feed conclusions back to doctors in the form of personalized guidance for each patient. Such

guidance will be vital in an area of increasingly complex treatments tailored to the genetics of each patient's tumor.

To maximize the benefits of these efforts for patients and to achieve consistent, high-quality care, ASCO recommends Congress and the Administration work with the oncology community to pursue a national oncology quality measurement system that is efficient, meaningful and relevant to oncology professionals and their patients. Further, advancing rapid-learning health systems such as ASCO's CancerLinQ, which has the potential to dramatically improve oncology care, will require engagement by payers and policymakers to have the greatest impact.

Need for a Strong Investment in Research and Changes to the Cancer Care Delivery System

ASCO looks forward to working with the committee to support a full investment in the NIH and NCI and to ensure that older Americans are considered in federally funded research. We further look forward to working with you to avert the impending crisis in access to cancer care by implementing sound policies that protect access to cancer care.

The SIOG 10 Priorities Initiative

Yunnan, China - © Image by S. Beck

International Society of Geriatric Oncology

Société Internationale d'Oncologie Gériatrique

The SIOG 10 Priorities Initiative

Project Leader:

Martine Extermann - Moffitt Cancer Center, Tampa, Florida, USA

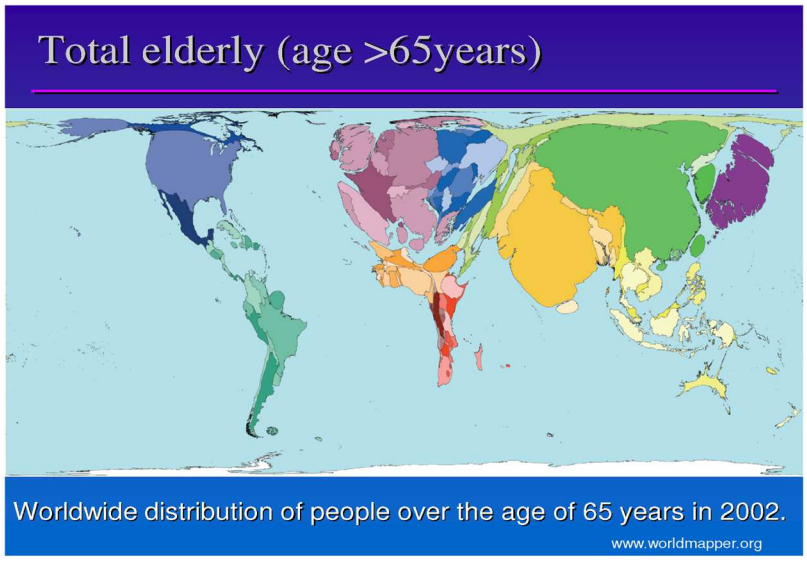
Writing Committee:

Matti Aapro - Clinique de Genolier, Genolier, Switzerland
Riccardo Audisio - St Helens Hospital, Liverpool, UK
Lodovico Balducci - Moffitt Cancer Center, Tampa, Florida, USA
Jean-Pierre Droz - Centre Léon Bérard, Lyon, France
Christopher Steer - Border Medical Oncology, Wodonga, Australia
Hans Wildiers - UH Gasthuisberg, Leuven, Belgium
Gilbert Zulian , Hôpital de Bellerive (Palliative Medicine) Geneva, Switzerland

***Note**: all SIOG National Representatives and other participants involved in this initiative are listed at the end of the document.*

Introduction

Thanks to the global improvement in health care and living conditions, the world's population is aging. In developed countries, half of the cancers already occur in patients aged 70 and older, so geriatric oncology is rapidly coming to the foreground of oncology practice. In booming Asian nations, such as South Korea or Japan, the aging trend is particularly striking. In fact, by 2050 the majority of older persons will live in developing countries. As older patients have a very variable health status, the need for proper integration of an oncologic and a geriatric approach has become increasingly important. Incorporating geriatric principles into routine oncology care will serve to optimize the treatment and reduce the functional impairment of older cancer patients and its associated social and personal costs. Given the size of the problem, governmental health agencies, international and local organizations, academic institutions, and the medical community at large will need to identify and primarily target the most pressing issues. Expert input is invaluable in this process, and therefore SIOG decided to build an expert consensus on top priorities within the field of geriatric oncology, based on the input from experts from each world continent. This document can be used for policy making, development of research strategies, and public information, with the final goal of improving care for all older patients with cancer.



The SIOG 10 Priorities Initiative

The International Society of Geriatric Oncology (in French: Société Internationale d'Oncologie Gériatrique, SIOG) is a multidisciplinary society that unites experts in the field of geriatric oncology from throughout the world. As such we launched an initiative to define what, in the experts' opinion, should be the top 10 priorities for the development of geriatric oncology worldwide. This document represents the fruit of our efforts. Our hope is that it will help guide the decision makers at all levels in addressing the global challenge of an aging cancer population. We would welcome any feedback from the various stakeholders as our objective is to foster a continuing process of improvement in the care of these senior patients.

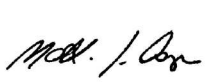
Methods

Over 2009 and 2010, SIOG asked its national representatives (see list in Appendix) to identify the top 10 global priorities in developing the field of geriatric oncology. Their answers were collected by a writing committee and a consensus was built. A second round of questions was then circulated asking the representatives to contribute how these priorities would translate more concretely in their national setting. The writing committee then assembled these answers and redacted a region by region translation of the 10 global priorities. All national representatives had the opportunity to review the final manuscript.

For SIOG:

Martine Extermann
Project Leader
Immediate Past SIOG President

Riccardo Audisio
SIOG President



Matti Aapro
SIOG Executive Director

Dr. Martine Extermann with Dr. Paul Calabresi, first SIOG President

SIOG 10 priorities initiative: General Priorities

Education

1. Increase public awareness of the worldwide cancer in the elderly epidemic and the need for a specific approach to address the problem
    - Political institutions (Health ministries, international organizations)
    - Medical societies
    - Advocacy networks, media, to develop a more positive image of older cancer patients

2. Integrate geriatric oncology in the curricula for medical and nursing education, both during studies and post-graduate education

3. Address the shortage of specialist oncologists/geriatricians & allied health staff in geriatric oncology.
    - Develop/support specific training programs
    - Increase/develop funding to foster academically oriented specialists able to address the populations not targeted by traditional oncology studies

Clinical practice

4. Develop interdisciplinary geriatric oncology clinics, especially in academic institutions and comprehensive cancer centers

5. Integrate geriatric evaluation (including comorbidities) into oncology decision-making and guidelines

6. Address issues of access to care, including the needs of the caregiver

Research

7. Develop, test and disseminate easy screening tools to enable proper referrals to multidisciplinary clinics and encourage integrated approaches between oncologists and geriatricians

8. Create a clear and operational definition of vulnerability/frailty applicable to oncology

9. Increase the relevance of clinical trials for older patients:
    - Require large phase III trials to oversample older cancer patients in order reach a meaningful percentage of their cohorts, and to structure their analysis to provide results specific and pertinent to this population
    - Extend phase II and III trials to patients with high levels of comorbidity or functional impairment with stratified accruals or extension cohorts
    - Design specific trials for older cancer patients

10. Promote multidisciplinary, basic/translational research on the interface of aging and cancer.

Practical suggestions for implementation by regions

EDUCATION

1. **Increase public awareness of the worldwide cancer in the elderly epidemic and the need for a specific approach to the problem**

   - **Political institutions (Health ministries, international organizations)**
   - **Medical societies**
   - **Advocacy networks, media, to develop a more positive image of older cancer patients**

Africa

In Africa older people represent a small percentage of the overall population, however this fraction is rapidly growing. There is little public or professional awareness of the issue. There is need for a change in the culture among the public and health professionals towards the senior patient with cancer. The aim would be to ensure that older patients receive a better chance at treatment and maintenance of independence for whatever duration of life they have left. There is a need to clarify that the costs of appropriate treatment are outweighed by the benefits of avoiding incapacity, and the related care burden for relatives, health care authorities, and society as a whole.

Asia

The proposed ideas followed two main tracks. The first one is to make people aware that cancer can be successfully treated in older patients. For example, by showcasing "success stories" of prominent people who overcame cancer at an advanced age, or making caregivers aware that older relatives deserve the same medical attention as younger people. There is also a need to transform not only the knowledge, but also the attitudes of health professionals towards the elderly. The second issue is to address the political concerns for proper use of resources, as some governments are very cost-conscious. It is important that oncologists continue to emphasize the cost-effectiveness of proper management of older cancer patients.

Outpatient clinic at DRO, Sarawak, East Malaysia

Europe

Several European governments have taken initiatives to develop geriatric oncology: grants for research (e.g. Belgium, France), creation of a network of expert onco-geriatric units (e.g. France). Geriatric oncology needs to be integrated further in national cancer plans, as this is a major way cancer outcomes can be improved at a national level. In the Netherlands The National Care for the Elderly Programme ("Nationaal Programma Ouderenzorg") was designed to improve care for elderly people with complex care needs. Practitioners, patients and supporters can create or collaborate with advocacy societies (e.g. Austria: "Senioren-Krebshilfe" (Senior Cancer Aid), Germany: No Ca Society, France: GEPOG), which could provide funding and political pressure. Question sessions addressing politicians directly could also be useful. Lecturing in the professional and in the public settings would make people aware of the importance of the problem. Geriatric oncology professionals and advocates should work at improving the image of geriatric medicine as a discipline among students, general practitioners, and head of departments, e.g. by inviting "star speakers". Geriatric Oncology working groups and task forces are also active within some medical societies and can serve as leverage to emphasize the field (e.g. GeriOnNe in the Netherlands). More need to be developed.

North America

Key political educational targets are legislative representatives and key persons in the national health systems (e.g. Medicare). There is a need to show that proper care can save lives and money. Medical societies have several working groups in geriatric oncology: ASCO is very active, other societies have variable activity levels. A key education need is to show that evaluation tools are available and can change outcomes. So far, local and national media have been underutilized for advocacy. We should emphasize that improving the care for older patients will mean better quality of life and treatments appropriately tailored to individual patients.

Oceania

In Australia, one strategy may be to commission a credible report using local data to document the expected increase in cases and the shortfall in medical resources. The role of geriatric oncology as part of the solution could be highlighted. This data can then be used as a lobbying tool. Meetings with high-level politicians will be required to facilitate change. Continued engagement with the oncologic, hematologic, and geriatric communities through medical societies is needed in a multidisciplinary fashion (e.g. meeting presentations, surveys of society members about practices and attitudes). Consumer groups and mainstream media should be engaged by presenting good stories of successful treatment in older people or highlighting cases of discrimination.

2. Integrate geriatric oncology in the curricula for medical and nursing education, both during studies and post-graduate education

Africa

The principles of geriatric assessment should be integrated in the undergraduate medical and nursing curricula, and geriatric oncology in the post-graduate curricula.

Asia

The needs of each country appear variable. In some, like India, oncologists need to interact with the geriatrics department/sections in the department of internal medicine to examine the current incidence of cancer in their older population and demonstrate the benefits of working together. In other countries, such as Singapore, geriatric medicine itself would need first to be reinforced. Finally, in some countries, the work is at the very beginning and initial educational opportunities are probably best available at the postgraduate level.

Europe

In many countries specific post-graduate courses are available for primary physicians and specialists alike, as well as for nurses and allied health professionals. They range in scope from 2-3 day courses to full tertiary programs with diplomas. In some countries though, setting up such courses will represent a real challenge because the practice of oncology is fragmented between organ specialists. Better integration of oncology practice there might facilitate training. Some countries are starting to formally introduce geriatric oncology in their medical studies curriculum (e.g. Slovakia, France, Norway). There is an opportunity for societies such as SIOG to give guidance on graduate and specialty training core curricula items. Visiting professorships in geriatric oncology might be initiated at medical universities.

Giorgione: Ritratto di Vecchia (Venezia, Galleria dell'Accademia)

North America

Presently, geriatric oncology is minimally or not represented in the general ASCO/ESMO or in the Canadian fellowship curricula. Evidence-based items should be added. Dual geriatric oncology fellowships are accepted by the American Board of Internal Medicine in the US, but a limited number are active. For continuous education, ASCO just updated its geriatric oncology online curriculum. Geriatric oncology should also be introduced in medical studies (e.g. in a multidisciplinary oncology clerkship month), and in nursing training and certification. It should be integrated also in the post-graduate training of other specialties, such as surgery or gynecology. Conversely, the amount of oncology should be increased in geriatrics training.

Oceania

In Australia there is a need to advocate for changes in the curricula at all levels. This can be done by direct approaches from oncology and aged care organizations and academic leadership from dual trained clinicians.

South America

Discussing the integration of geriatrics and oncology curricula is the first step that needs to be taken.

Global

A process to support and promote geriatric oncology CME activities and conferences all over the world should be developed.

3. Address the shortage of specialist oncologists/geriatricians & allied health staff in geriatric oncology

- **Develop/support specific training programs**
- **Increase/develop funding to foster academically oriented specialists able to address the populations not targeted by traditional oncology studies**

Asia

The needs are again variable. Some countries, such as India, could propagate the US geriatric oncology fellowships model and discuss how it can be modified to suit local needs. In other countries, such as Malaysia, the general medical shortage, including that of geriatric and oncology specialists needs to be addressed first. In some countries, such as Singapore, cross-training might be feasible, but financial compensation is needed to support the longer duration of training.

Europe

Several countries are adopting a cross-training approach as part of continuous education (e.g. French CE courses, Belgian common society meetings…). In other countries, a combined certification derived from the combined US fellowship model appears more desirable (e.g. Germany, Slovakia). Some countries, such as the Netherlands, have a formal fellowship in geriatric oncology. The development of academic positions should include research possibilities to target this underserved and not traditionally targeted population, whether academic or pharma-funded, depending on the funding structure of clinical research in each country. A concern is that in several countries, oncologic care is fragmented among organ specialists, for whom it is only part of their practice. In that setting, having geriatric oncologists find their place and have patients referred can be challenging. Multidisciplinary consultations might be a possible solution. In certain countries, such as Switzerland, there are already a handful of specialists with dual certification in oncology and geriatrics, and a new generation is slowly emerging.

North America

In the US, initiatives like the combined geriatric oncology fellowships, the P20 grants to develop geriatric oncology programs in cancer centers, or the Cancer and Aging Research Group need follow-up and development. Academic oriented specialists are presently not a priority politically in Canada, but pushing for the training of more geriatricians may lead to a higher potential for multidisciplinary care.

Oceania

In Australia, dual training in geriatric oncology is currently unattractive in part due to the length of time required to complete training in both disciplines. There is currently no flexibility to enable a combined program. We need to work with the Royal College of Physicians (RACP) to create a subspecialty and streamline the existing training program.

Research and infrastructure funding comes from government, philanthropy and pharma. Multipronged approaches to gain funding are required dovetailing with the advocacy mentioned above to increase awareness and the need for change; recognizing this will cost money.

CLINICAL PRACTICE

4. Develop interdisciplinary geriatric oncology clinics, especially in academic institutions and comprehensive cancer centers

Africa

In a country like Egypt, the general trend of practice is in separate disciplines with referral or consultation between practitioners on a case by case basis. A good approach would be to integrate a specific clinic or shift in a general oncology clinic attended by motivated oncologists/geriatricians. Building upon the existing work culture would facilitate a progressive change towards an interdisciplinary model. This model whilst being less familiar for clinicians will enable enhanced care of older patients with cancer.

Asia

Two approaches are suggested as feasible. One is to develop and integrate these multidisciplinary clinics as a part of a comprehensive cancer center. Another approach is to develop combined weekly rounds.

Europe

This process is at various levels of development depending on the country. In some countries, a cultural change needs to happen by developing dialog between geriatricians and oncologists who have had little interaction so far (e.g. Netherlands, Norway, Slovakia). Some countries see the development along the line of regular pluridisciplinary consultative meetings rather than separate clinics (e.g. Belgium, Switzerland). France is further along in the process and is developing a regional geriatric oncology unit in each of its 15 regions. Programs in development might use the opportunity to visit established programs abroad for training. The integration of geriatric oncology units should become part of Comprehensive Cancer Center accreditation.

North America

Two models are possible: Dually trained oncologists leading geriatric oncology programs or collaborative models with geriatric teams supporting oncology teams. Several comprehensive cancer centers are now hiring geriatricians.

Oceania

Australia: Set up examples in large centers and encourage others to model clinics on existing infrastructure. The best model of care will vary according to the infrastructure available. There is a successful geriatric oncology clinic in Adelaide whose experience can serve to develop similar programs.

South America

In Brazil, the first need is to integrate geriatric and oncology education before the development of geriatric oncology programs can follow. Because overall life expectancy is still low, such programs would certainly be limited in the beginning to large referral centers.

5. Integrate geriatric evaluation (comorbidity included) into oncology decision-making and guidelines

Asia

There is a general consensus that a comprehensive geriatric assessment (CGA) should become part of routine practice and that this is a crucial point to prevent suboptimal care in older patients. Local physicians with an interest in geriatric oncology should meet to design guidelines adapted to each country. The practical implementation of multidisciplinary clinics is challenged by the competing interests of the few geriatricians available.

Europe

The present challenge is to convince oncology colleagues to use a geriatric evaluation in their daily practice. Several solutions are suggested: Generalize the screening tools in the practice, continue to publish convincing data, ask as reviewers or in letters to editors about lack of control for geriatric factors in published papers, integrate the geriatric decision process into guidelines. Attention also should be paid to national journals, to reach colleagues who are not fluent in English. Local geriatric oncology societies have a clear advocacy role to foster. Reimbursement issues need to be addressed, as in some countries, such as Belgium, geriatric consultations are only reimbursed for hospitalized patients and not for ambulatory patients who are the majority of cancer patients.

North America

A strategy is to promote the inclusion of a geriatric evaluation in references such as ASCO's geriatric curriculum, or the NCCN guidelines with displays for older patient subgroups. We should continue to accumulate data to show that an integrated approach leads to interventions that can optimize disease specific and overall care. Practical validated tools need to be diffused.

Oceania

The priority in Australia would be to create a useful, feasible, accessible tool for oncologists to use and to ensure that the infrastructure is available to handle the results. Using new technologies and creative database integration would help increase its attractiveness to clinicians and enable

data collection and pooling. Once a tool has been designed and established for use in the Australian context, lobbying government to ensure clinicians are paid to use it would be vital to its ongoing utility. There is a call to push a single, SIOG-branded assessment tool.

6. Address issues of access to care, including the needs of the caregiver

Asia

The situation varies by country. For example, in Sarawak (Malaysia), where various ethnic groups are present, access to care mostly depends on the younger generation, especially for those who live in rural areas. Hence the education of the public plays a vital role in whether the elderly have access to care or not. In Singapore, the approach needs to be integrated into the CGA.

Europe

As most European countries have universal healthcare coverage (private or public), finance-related barriers are minimal. **Age limits should be discouraged in guidelines**. Although support for caregivers of patients with Alzheimer's disease or caregivers of younger patients has been developed with help from advocacy societies, there is still a need for the development of similar support for the caregivers of older cancer patients. Studies in this field are required to provide crucial objective data on these caregivers role, needs, and access to care. The formation of caregivers should be developed.

Very young...100 year-old lady - Image from Dr JP Droz, former SIOG President

North America

Access to care is not considered a problem in the Canadian system. In the USA, there are issues with the cost of oral therapies and their coverage by Medicare. Concerning physical/social barriers and caregiver support, pilot studies are needed, with later expansion to accrual in cooperative groups.

Oceania

In Australia, there is no significant financial problem with access to care because of universal coverage. Other aspects of access restriction are more subtle. There is a need to campaign

against ageism from all levels of health providers, at the same time being mindful of health economics. Being proactive in the study of health economics may be required.

RESEARCH

7. Develop, test and disseminate easy screening tools to enable proper referral patterns to multidisciplinary clinics or integrated approaches between oncologists and geriatricians

Asia

Some form of easy adaptable tool may be developed for busy clinics that may facilitate access to oncology care, given the shortage of geriatric oncology specialists.

Europe

At the present time, the major issue is to sort among the available screening tools . There is a call by several national representatives for a joint effort from SIOG to identify and support 1-2 consensual screening tools with the best performance for diffusion.

North America

At this time, the need is to present and compare the geriatric assessment evaluations, and encourage participation in various studies testing and using them. In Canada, there is a need for someone or a group to champion and develop their use.

Oceania

As in Europe, there is a call to develop a SIOG sanctioned and branded tool, and have facts to back up its effectiveness, its ease of use, and its ability to pick up geriatric syndromes.

Global

Comment from the SIOG leadership team: At the present time, SIOG deems best to let data accumulate and let tools be sorted spontaneously based on the evidence that emerges.

8. Create a clear and operational definition of vulnerability/frailty applicable in oncology

Asia

Simple tools are needed, as well as moving towards more objective biological markers and correlating with clinical outcomes for validation.

Europe

A SIOG working group might develop this definition as pertains to cancer patients. Trials could also establish a network prospectively collecting data. An avenue would be to convince politicians to integrate geriatric oncology networks as a topic in the EU research framework. The geriatric literature should be tapped to integrate their findings into geriatric oncology research, and

reciprocally, oncology literature should be integrated in aging research. A new initiative to define frailty was recently started within academic geriatrics, led by Simon Conroy in the UK. The global effort should be linked to academic geriatricians who could be targeted in the European Academy for Medicine of Ageing (EAMA) and in the European Union of Geriatric Medicine Specialty (EUGMS). At the present time, geriatric oncology is briefly touched, whereas frailty is extensively covered in their courses.

North America

Geriatric researchers should be involved. Exploit what has been done by other experts in the field, review and adapt it. Beyond the definitions, the tools should be used and associated with specific interventions that will change treatment and outcomes.

9. Increase the relevance of clinical trials for older patients:

- **Require large phase III trials to oversample older patients in order reach a meaningful percentage of their cohorts, and to structure their analysis to provide results specific and pertinent to this population.**
- **Extend phase II and III trials to patients with high levels of comorbidity or functional impairment with stratified accruals or extension cohorts**
- **Design specific trials for older cancer patients**

Africa

Multicenter, multinational studies with inclusion criteria that allow senior cancer patients to participate should be encouraged. Even more appropriate would be studies specific to older patients.

Asia

Research is mostly conducted by taking part in international trials rather than developing local ones. Participating in international geriatric oncology consortiums might be a way to address this priority.

Europe

The priority is to find ways to generate incentives towards investigators and sponsors for developing relevant trials. The majority of clinical trials are supported by the pharmaceutical industry, financially but often also in terms of design. One way to convince sponsors could be to have EMEA require that this population be addressed in clinical trials. Another suggestion is that academic funding might be restricted if elderly patients are inadequately covered. This would require establishing national/international criteria to demonstrate adequate recruitment of elderly patients. Financial support of trial extensions to older patients should be increased. Specialist cooperative groups such as the French GERICO could collaborate with larger cooperative groups such as EORTC to design targeted trials. A Summer school run by SIOG could be established for junior researchers. Alternatively, a geriatric oncology day could be integrated

and elderly specific protocols encouraged in the "Methods in Clinical Cancer Research" workshops.

North America

A key objective is to develop this aspect in cooperative groups and other consortia: CALGB has some activity. We should raise the issue of the adequacy of the Common Terminology Criteria for Adverse Events in their present form for measuring toxicity in older patients. Toxicity should be stratified by age. In Canada, geriatric oncology is still too small to initiate phase III trials but will participate in multinational trials.

Oceania

Australia: Upper age limit practices should be eliminated in clinical trial inclusion/exclusion criteria. Geriatric oncology researchers need to approach all clinical trial organizations and become part of the scientific advisory committees. Clinical trial organizations need to think about clinical trials in the frail and poor performance status patients. We need to advise in this regard. To enable this, governments and trial bodies need to be persuaded that cancer in the elderly is a funding priority and thus enable good research with appropriate funding.

South America

In Brazil, funding is lacking to promote local clinical and translational research. Taking part in multicentric trials is the reality available in the immediate future.

10. Promote multidisciplinary basic/translational research on the interface of aging and cancer

Asia

In some countries, such as Malaysia, geriatric oncology is very new to most health professionals, and there is an urgent need to educate them. One way would be to begin with basic science research. With an increase in aging population globally, the underlying principles of care of the elderly cannot be more emphasized. In other countries, such as Singapore, an active research agenda is in progress.

Europe

Two common priorities are: First, to better integrate this topic in SIOG and other meetings and to create a translational task force within SIOG to which to invite basic scientists. Second: to develop the funding support. Specialized cooperative groups, such as GERICO, could integrate translational aspects in their trials. Research Ministries should be prompted to set up national research programs in the field. European Union representatives should also integrate this topic in EU research frameworks programs. Pharmaceutical industry research should be encouraged to develop specific susceptible to improve the outcomes and quality of life of the elderly presenting with many diseases, disorders, and disabilities, along with their cancer, as there is mounting evidence that aging and comorbidity influence the tumor biology, behavior, and response to treatment.

North America

In the US, there is a need for more specific expertise in the NIH study sections and better targeting of this area in program announcements and requests for applications. AACR and similar translational organizations should play an important role in promoting this type of research. In Canada, this is not yet perceived as a priority.

Oceania

In Australia, the focus should be on continued interaction with the aged care and gerontology community. Collaborations need to be promoted.

Image Simon Howden – freedigitalphoto.net

APPENDIX - The following SIOG members contributed to this monograph:

Project leader: Martine Extermann

Writing Committee: Matti Aapro
Riccardo Audisio
Lodovico Balducci
Jean-Pierre Droz
Christopher Steer
Hans Wildiers
Gilbert Zulian

National representatives (Denotes current NRs*) and other participants:**

Salah-Eldin Abdelmoneim (Egypt)*
Lodovico Balducci (USA)*
Giordano Domenico Beretta (Italy)
Jan Willem Coebergh (The Netherlands)
Hervé Curé (France)*
Kazuo Dan (Japan)*
Beena Devi (Malaysia)*
Alexandru Grigorescu (Romania)*
Jørn Herrstedt (Denmark)*
Arti Hurria (USA)
Maryska Janssen-Heijnen (The Netherlands)
Dimitrios Kardamakis (Greece)*
Siri Kristjansson (Norway)*
Jean Latreille (Canada)*
Robert Leonard (United Kingdom)*
Stuart Lichtman (USA)*
Vicki Morrison (USA)*
Arash Naeim (USA)*
Hans Nortier (The Netherlands)*
Dearbhaile O'Donnell (Ireland)*
Demetris Papamichael (Cyprus)*
Purvish Parikh (India)*
Gumersindo Perez Manga (Spain)*
Donald Poon (Singapore)*
Reinhard Stauder (Austria)*
Christopher Steer (Australia)*
Maria Wagnerova (Slovakia)*
Ulrich Wedding (Germany)*
Hans Wildiers (Belgium)*
Manuela Zereu (Brazil)*
Gilbert Zulian (Switzerland)*

February 2011

The International Society of Geriatric Oncology

is a member of UICC

Margaret Barton-Burke, PhD, RN, FAAN
President,
Oncology Nursing Society

Testimony for the Record
Before the Senate Special Aging Committee
Hearing Entitled
"The Fight Against Cancer: Challenges, Progress, and Promise"

Wednesday, May 7, 2014

Chairman Nelson, Ranking Member Collins, and members of the Committee, on behalf of the Oncology Nursing Society (ONS), I would like to thank the Senate Special Aging Committee for the opportunity to share our views on the importance of cancer research. We hope you will consider our comments regarding the potential health benefits for all Americans of a strong funding commitment to medical research at the National Institutes of Health (NIH). ONS is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas.

Our written testimony will discuss the need for medical research funding for NIH as Congress works to complete the Labor, Health and Human Services, and Education appropriations bill for fiscal year (FY) 2015. We encourage Committee members to support investments in biomedical research as you and your colleagues weigh the difficult choices that need to be made with respect to the budget and reducing the deficit. We would be happy to discuss our thoughts and principles with you, as well as any other questions you may have going forward.

Considerable progress has been made in the fight against cancer because of the dedicated work of researchers, clinicians, patients, and advocates. ONS again thanks the Committee for the opportunity to provide feedback and looks forward to working with you to address the projected increase in the incidence of cancer with an older population.

Cancer has become the nation's leading cause of death. Each year in the United States, approximately 1.66 million people are diagnosed with cancer, another 580,000 die from this terrible disease, and more than 13.7 million Americans count themselves among the growing community of cancer survivors.

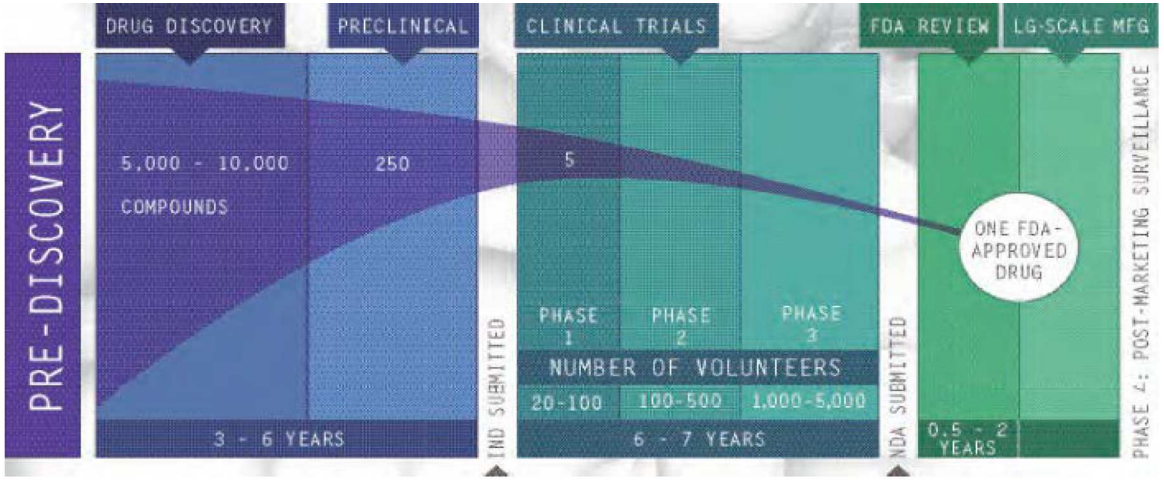
The NIH is our country's premier institution for medical research. Funding for the NIH directly promotes and improves the health of individuals, families, communities and populations. Through institutes such as the National Cancer Institute (NCI), the National Institute of Nursing Research (NINR), and the National Center for Minority Health and Health Disparities (NCMHD), researchers are working tirelessly to develop new cancer screening tools and treatment to sustain and expand quality-of-life and symptom management.

ONS members have been engaged in many areas of research to improve oncology care for their patients. The Committee heard testimony from Valerie Harper, Actress and Advocate with Leptomeningeal

carcinomatosis (LC), a rare complication of cancer in the brain. Through NINR, our nurses have completed research on caregiving for survivors of brain tumors. You also spoke with Sen. Collins' former staffer Baynard W. Kennett (Chip), who shared the story of his battle with Stage IV terminal ALK and non-small cell lung cancer. ONS nurses funded by NCI have studied home telemonitoring for self-management education of patients with lung cancer.

In the last year alone, oncology nurses completed projects such as "Interdisciplinary Training of Nurse Scientists in Cancer Survivorship Research," "Personal Patient Profile – Prostate: Testing and Implementation in Health Networks," and "A Brief Patient--Controlled Intervention for a Symptom Cluster in Advanced Cancer." NIH research funding is a vital investment towards advancing quality cancer care. A strong commitment to funding for the NIH makes projects possible that reduce and prevent suffering from cancer.

Thank you again for taking into consideration our written comments. I encourage you to contact me or Alec Stone, MA, MPA, Director of Health Policy, Oncology Nursing Society at astone@ons.org if you have any questions. The Oncology Nursing Society and I look forward to working with the Committee to strengthen our nation's commitment to cancer research.



Step One: Pre-discovery. Before any potential new medicine can be discovered, scientists work to understand the disease course, and to unravel the underlying cause of the condition. For instance, studying how genes are altered, how that affects the proteins they encode and how those proteins interact with each other in living cells, how those affected cells change the specific tissue they are in and finally how the disease affects the entire patient. This is Basic Research, and it is process of working with basic research to translate it efficiently into action steps or new discovery that is often called translational research. When this funding is cut, it is catastrophic for development of any new medicines.

Step 2: Drug Discovery and Pre-Clinical Phase. This is the period where scientists search for a molecule, or "lead compound," that may act on their identified target to alter the disease course.

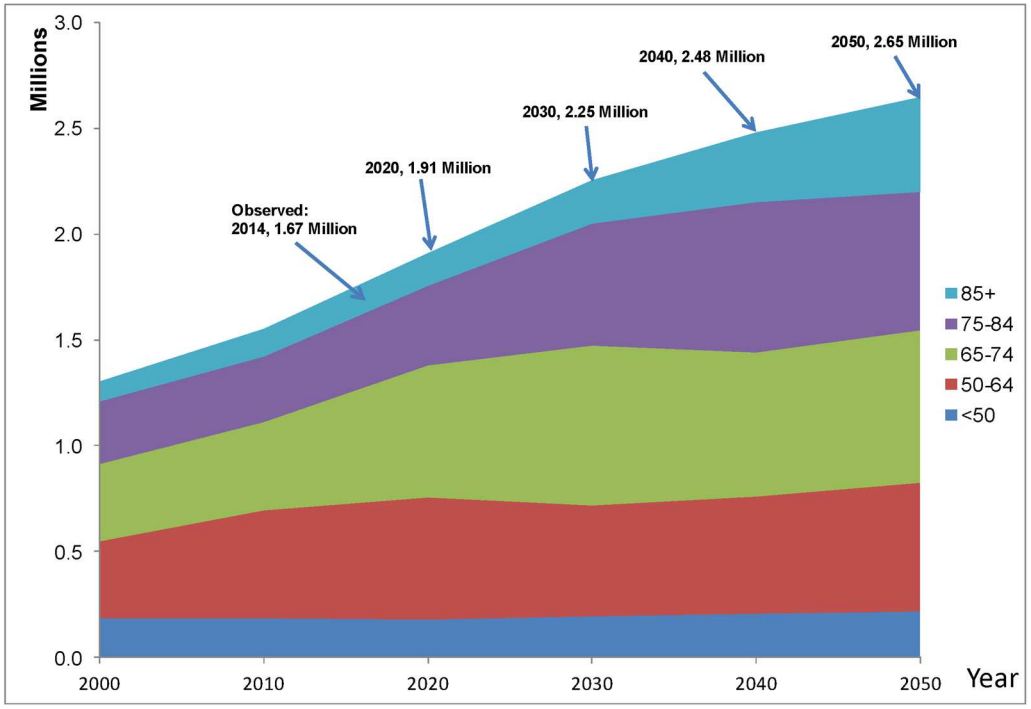
Step 3: Investigational new drug application. Before any clinical trial in humans can begin, the researchers must file an Investigational New Drug (IND) application with the FDA.

Step 4: Clinical Trials: Before a drug is approved for broad use and marketing, it must undergo three clinical trial phases.

Step 5: New Drug Application. Upon successful completion of all clinical trial phases, a drug can apply for a new drug application which approves the drug for large scale manufacturing.

Step 6: Post-Marketing Surveillance. Final Additional data is submitted once the drug has been in use in the broad population.

Projected Number of US cancer cases for 2000 through 2050 based on projected census population estimates and age-specific cancer incidence from cases diagnosed in 1995-1999 in the SEER and NPCR areas.



Source: Annual Report to the Nation, Featuring Implications of Age and Aging on U.S Cancer Burden, Cancer, 2002.

AMERICAN COLLEGE OF SURGEONS

Inspiring Quality:
Highest Standards, Better Outcomes

The American College of Surgeons Commission on Cancer

Statement

before the

United States Senate Special Committee on Aging

Hearing: The Fight Against Cancer: Challenges, Progress, & Promise

May 7, 2014

The American College of Surgeons Commission on Cancer (CoC) is grateful for the opportunity to provide a statement to the United States Senate Special Committee on Aging for the May 7, 2014 hearing entitled, "The Fight Against Cancer: Challenges, Progress, & Promise."

The CoC is a consortium of Fellows of The American College of Surgeons and representatives from fifty-three professional organizations dedicated to improving survival and quality of life for cancer patients. The CoC sets comprehensive, patient-centered standards and collects standardized data to measure cancer care quality in approximately 1,500 CoC accredited hospitals in the United States. In its efforts to promote groundbreaking advances in cancer treatment, the CoC has long supported investments in cancer research at the National Institutes of Health (NIH) and the National Cancer Institute (NCI). The CoC upholds accreditation standards which require cancer centers provide information about cancer-related clinical trial opportunities and meet the established clinical trial accrual thresholds. The CoC is very pleased to see the Senate focus a hearing dedicated to the fight against cancer and we look forward to working with the Committee on Aging to improve the lives of cancer patients and their families.

The impact of age on cancer occurrence has arrived. This is the result of multiple converging factors: a worldwide decrease in child bearing, changing patterns of mortality with improved life expectancy and, most importantly, the emergence of the baby boom generation (those born between 1946 and 1964). Aging is recognized as the major risk factor for the development of malignancies and therefore the majority of cancers affect the older population (generally defined as being greater than 65) disproportionately. Currently, there are approximately 39 million Americans age 65 and older, up from 25.5 million just 30 years ago. Sixty percent of newly diagnosed malignancies and 70 percent of all cancer related deaths occur in people over the age of 65. Thus, the cancer incidence rate for persons 65 and over is ten times greater than the rate for those under 65; the mortality rate is 16 times greater for the above described age groups.

Major strides have been made in the treatment of over 200 cancers in the past 50 years. For example, long term survival rates for breast cancer and acute lymphocytic leukemia in children now commonly exceed 90%. This is due in large part to the many investment dollars which the federal government has expended, particularly through the NIH and the NCI, amongst many others. The budget cuts known as "sequestration" have reduced the NIH's budget by $714

million resulting in 640 fewer research grants in 2013. Fiscal-year budgets have declined yet the cost of research has increased. This trend is unacceptable.

Research dollars are desperately needed to improve early detection/diagnosis and treatment of all cancers. Studies directed, particularly to the "greying" population, must address characteristics of the aging process and seek to identify the molecular alterations in carcinogenesis and the accumulation of cancer causing mutations as they relate to this portion of the population. The biology of aging and the development of malignancies are well recognized, but only on a superficial level. More in depth understanding is lacking. Further, advances in the treatment of one cancer may cross-fertilize to the treatment of other cancers, including those in the younger population.

The aging patient is a complex patient. In addition to a cancer diagnosis, they must often deal with multiple comorbidities which may include coronary artery disease, hypertension, dyslipidemias, diabetes, renal failure, etc. These diseases and other disabilities may have a profound impact on both cancer treatment and recovery. Race and ethnic disparities must also be addressed.

Currently, there are 13.7 million cancer survivors in the United States – a number expected to grow to 18 million by 2022. Survivorship brings its own issues, namely the side effects of the treatments themselves. Many drugs used in treatment result in long term toxicities which affect the cardiovascular system, may lead to an increase in osteoporosis and potentiate thromboembolic events. In addition, the development of secondary malignancies presents a significant concern requiring ongoing surveillance beyond the primary malignancy. Pain management and palliative care are also in need of research studies to accomplish the most effective, evidence-based approaches. These issues are particularly germane to our aging population. Finally, it should be noted that beyond "survivors" cancer extends to the community of caregivers and their quality of life as well.

Prevention is another major issue in the setting of malignancy and aging, as longevity is increasing. Many cancers are preventable and half, if not more, are due to obesity, poor dietary habits, lack of exercise and tobacco use. Education regarding these risk factors and technologies for the successful implementation of healthy lifestyles needs to be better understood. The

financial impact on the cost of health care would be enormous if such measures would be adequately funded and undertaken.

The multidisciplinary CoC establishes standards to ensure quality, multidisciplinary, and comprehensive cancer care delivery in health care settings; conducts surveys in health care settings to assess compliance with those standards; collects standardized data from CoC-accredited health care settings to measure cancer care quality; uses data to monitor treatment patterns and outcomes and enhance cancer control and clinical surveillance activities, and develops effective educational interventions to improve cancer prevention, early detection, cancer care delivery, and outcomes in health care settings. The CoC's standards continue to evolve and keep pace with the science, but a strong federal investment in new discoveries is essential to continuous improvement in the ways we prevent, diagnose and treat cancer.

Thank you again for your focus on the fight against cancer. The Commission on Cancer strongly supports the allocation of research dollars to study the aging/cancer relationship with the hope that a cure for all cancers can soon be found. We look forward to working together with you on this important mission.

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