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3 HEARING ON ``NCI CANCER RESEARCH: TODAY'S PROGRESS;

4 TOMORROW'S CHALLENGES''

5 TUESDAY, MARCH 23, 2010

6 House of Representatives,

7 Subcommittee on Health

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The Subcommittee met, pursuant to call, at 2:05 p.m., in

11 Room 2322 of the Rayburn House Office Building, Hon. Frank

12 Pallone, Jr. [Chairman of the Subcommittee] presiding.

13 Members present: Representatives Pallone, Eshoo, Green,

14 Capps, Schakowsky, Baldwin, Christensen, Castor, Space,

15 Waxman (ex officio), Shimkus, Buyer, Burgess, Gingrey and

16 Barton (ex officio).

17 Also present: Representative Biggert.

18 Staff present: Sarah Despres, Public Health Counsel;

Anne Morris, Professional Staff; Stephen Cha, Professional Staff; Alvin Banks, Special Assistant; Aarti Shah, Minority Professional Staff; Clay Alspach, Minority Counsel; and Ryan Long, Minority Professional Staff.

Mr. {Pallone.} I call the hearing to order.

Let me mention that votes were just called, so we will try to do--maybe we will see if we can get in the three people that are here, or at least myself and Mr. Shimkus, and then we will have to take a break and come back.

But let me say today, as you know, we are having a hearing on NCI Research: Today's Progress; Tomorrow's Challenge, and basically examining the cancer research efforts at the National Cancer Institute. It is a very important topic that is of great interest to many of my colleagues. Many of my colleagues have been asking us to have this hearing for some time.

Cancer is an ugly word. It is an even uglier disease. Unfortunately, cancer touches us all and everyone in this room has had either direct or indirect contact with cancer. Either a mother, a father, a brother, a sister, in almost all cases a friend has been diagnosed with some form of cancer. And some have fought the odds and survived. Others tragically have lost the battle. The bottom line is, far too many of us have lost people we care deeply about to this horrible illness. Cancer is the second leading cause of death in the United States. In fact, it accounts for almost every one in four deaths. Half of all men and one-third of

all women will develop cancer during their lifetimes, and today, millions of people are living with cancer or have had cancer.

The issue is a very emotional and personal one for me. In the spring of 2008, my mother was diagnosed with pancreatic cancer, and she passed away late that same year. Pancreatic cancer is obviously one of the diseases that we are looking at today in particular.

Fortunately, we have made great progress in cancer research over the last decades. Just 40 years ago, there were only 3 million cancer survivors. Today, 3 percent of the U.S. population has survived cancer. We have new therapies that specifically target the malignant tumors in an attempt to lessen the impact of the therapy on the patients. We have better screening and early detection methods which help identify cancer in the stages when it is more successfully treatable.

With the support of Congressional efforts over the next 2 years, NCI will grant $1.3 billion to cancer researchers across the money, and this money will go to fund additional grants for first-time investigators, thereby providing additional opportunities for the next generation of investigators and ensuring that the pipeline for new researchers remains stable. This additional funding will

also go to initiatives that are expected to propel us forward in our understanding of cancer in the near future including efforts on the cancer genome atlas. I want to find out more about that today obviously. Also, research on personalized cancer care and new therapy development, collaborative cancer care work, just to name a few.

Nevertheless, we face serious challenges regarding rare and deadly cancers. Cancers that have been termed the deadliest cancers have a 5-year survival rate of less than 50 percent. These cancers include ovary, brain, myeloma, stomach, esophagus, lung, liver and, of course, pancreas. Pancreatic cancer is the deadliest cancer with a 5-year survival rate of only 5 percent. Combined, the deadly cancers make up half of all cancer deaths yet they receive a fraction of the research funding as compared to other cancers. It is clear that we still know far too little about these cancers. We have no or limited early detection and screening. By the time one of these cancers is diagnosed, it has often progressed too far for treatment to be successful. And I know some of our witnesses here today will speak to these issues and we look forward to their comments and recommendations.

As I think you know, we are a legislative subcommittee and so when we have oversight hearings like this, they are

designed to try to see whether we should be legislating, so I want everyone to keep that in mind in terms of their recommendations as we move forward today.

[The prepared statement of Mr. Pallone follows:]

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Mr. {Pallone.} And now I would like to recognize our ranking member, Mr. Shimkus.

Mr. {Shimkus.} Thank you, Chairman Pallone, for holding this important hearing about the progress and the challenges we face in tracking rare forms of cancer.

I want to thank all the witnesses for being here today to help educate members on this issue.

I have long been a supporter of cancer research but my former legislative director, Ray Fitzgerald's, battle with gastric cancer brought this issue much closer to my heart. As Chairman Pallone said, everybody has personal stories and experiences.

I want to thank Ray's wife, Kristin, and their three young girls, Nora, Maggie and Lucy, who I think are hiding somewhere not disrupting--oh, they are back there--for testifying before the committee today. They were an inspiration to me and many others as they publicly shared the highs and lows of Ray's cancer. Kristin has continued to work tirelessly to expand efforts in the field of gastric cancer. I know her knowledge on the subject here today will help the committee advance efforts in that area. Also just for the record, she is a former Congressional staffer, having worked for Harris Faywall, who is well known in the health

legislative area, Judy Biggert and now our Republican leader, John Boehner. I also would like to thank Dr. Barker for being here today from the National Cancer Institute. I commend you and the NCI on the many things you do to make cancer curable, and I look forward to your institutional knowledge on what we can do from the federal side to progress our efforts in research on rare forms of cancer.

With that, Mr. Chairman, I yield back my time.

[The prepared statement of Mr. Shimkus follows:]

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Mr. {Pallone.} Thank you, Mr. Shimkus.

I think we have time for Mr. Gingrey, the gentleman from Georgia.

Dr. {Gingrey.} Mr. Chairman, I will waive my opening.

[The prepared statement of Dr. Gingrey follows:]

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Mr. {Pallone.} You want to waive? Okay.

Ms. Capps, our vice chair.

Mrs. {Capps.} Thank you, Mr. Chairman. Before I make a brief statement, I wish to insert for the record written testimony of the International Myeloma Foundation regarding NCI Cancer Research: Today's Progress, Tomorrow's Challenges.

[The information follows:]

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Mr. {Pallone.} Without objection, so ordered.

Let me--it has been very busy and crazy around here the last few days so I overlooked, and I do want to mention that not only is Lois Capps our vice chair and one of the hardest working members of this subcommittee but also she has taken a particular interest in this subject, asked that we have this hearing today, and I think is also developing legislation--

Mrs. {Capps.} Yes.

Mr. {Pallone.} --on some of this, so thank you.

Mrs. {Capps.} Thank you, Mr. Chairman, and thank you to our witnesses and to all of you for being here.

It is so appropriate in my opinion that we are holding this particular hearing just 2 days after our historic passage of comprehensive health reform legislation. After all, while our witnesses today will be able to highlight just how advanced and cutting-edge cancer research is in the United States, now passage of legislation will finally mean that more American patients can take advantage of the treatment and the therapies that you all have developed.

I am eager to learn from our witnesses today about the direction of cancer research and how we can develop better policies in Congress that mesh with the work that you are doing. I think we know now that collaboration is key and it

is important that legislation and funding are geared toward facilitating collaboration.

We also know that research is incomplete unless we also include research on best practices for providing cancer care in the clinical setting. I am particularly interested in that phase of it, but I see it as a collaboration with what you are doing. While it isn't the focus of today's hearing, I urge the chairman to consider holding a hearing in the near future to discuss this issue of cancer care as well.

With the passage of health reform, a lot of us are getting back to our other health care priorities that we have held long, and this is one of mine. I am proud to be working with Chairman Pallone and several members of this committee to prepare a House companion to one of Senator Ted Kennedy's priorities, the 21st Century Cancer ALERT Act. This bill will put emphasis on enabling federal research dollars to model the trends of modern cancer research. Additionally, it will focus on patients as survivors and the concept of living with cancer. With the right types of investment, we can truly put an end to the days of cancer as a death sentence as it has been for so many of our loved ones.

I look forward to continuing to work with the committee to advance this legislation, and I hope we can use what we learn today to perfect the language that we are developing,

and with that, I yield back, Mr. Chairman.

[The prepared statement of Mrs. Capps follows:]

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Mr. {Pallone.} I think, Mr. Buyer, there is maybe 3 or 4 minutes left. Do you want to go now or would you rather--

Mr. {Buyer.} I will reserve.

[The prepared statement of Mr. Buyer follows:]

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Mr. {Pallone.} Okay. Then we will go in recess until we have--oh, Donna, did you want to do your statement? The gentlewoman from the Virgin Islands, Ms. Christensen.

Mrs. {Christensen.} Thank you, Chairman Pallone and Ranking Member Shimkus. Thank you for holding this hearing.

You know, there is not one of us here whose life has not been touched by cancer, and in my 21 years of practice, my patients with cancer have given me some of the highest highs like an elderly lady with early-found colon cancer who is still surviving many years later, and some of the lowest lows such as women with breast cancer who came so very late that nothing could be done, and African Americans, while we may not have the highest incidence of many cancers, have the shortest survival rates and the highest deaths of any other population group in this country and so this hearing is very important to me personally and as chair of the Congressional Black Caucus's Health Brain Trust. If we look at some other population groups, cancer is already surpassed heart disease as a leading cause of death for Asian Americans and Pacific Islanders.

There has been a lot of progress that we are very proud of in cancer research at the National Cancer Institute and all of NIH is to be commended for the trans disciplinary

programs, the linking of genomics and cancer and advances in molecular biology and technologies. I don't know where the balance should be but I do hope that the role of environmental and behaviors is given adequate attention as well.

Of great concern given the disparities that exist in African American and the projections for even greater incidence of cancer in the futures is how are we going to be able to ensure that the new diagnostic and treatment modalities reach everyone and reduce rather than exacerbate the disparities that now exist. So I would like to know what progress is being made and including racial ethnic minorities and women adequately in clinical trials, and just as important, how many principal investigators are at minority-serving institutions, which is what would really help to increase our participation, which is very critical to reducing the longstanding disparities.

I would like to welcome you, Dr. Barker, and the other panelists on the second panel. We look forward to your testimonies. Thank you.

[The prepared statement of Mrs. Christensen follows:]

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Mr. {Pallone.} Thank you, Dr. Christensen.

So we will now recess, and I think there are three votes so I guess maybe 45 minutes, maybe less. The subcommittee hearing is in recess.

[Recess.]

Mr. {Pallone.} The subcommittee will reconvene. Now, I know that there were some that did not have a chance to do openings so we will have that now for those of you who didn't. I think next was the gentlewoman from Florida, Ms. Castor.

Ms. {Castor.} In the interests of time, I would really like to hear the witnesses so I will submit my opening statement for the record. Thank you, Mr. Chairman.

[The prepared statement of Ms. Castor follows:]

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Mr. {Pallone.} Thank you.

The gentleman from Texas, our ranking member.

Mr. {Barton.} Mr. Chairman, I will put my statement in the record. I agree, we need to get to the witness, but thank you for giving me the opportunity.

[The prepared statement of Mr. Barton follows:]

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Mr. {Pallone.} Thank you.

Ms. Eshoo.

Ms. {Eshoo.} Thank you, Mr. Chairman. I will put my full statement in the record, but let me thank you for having this hearing today.

I am pleased that our subcommittee has the stamina to push forward, especially on this important hearing because cancer is the second leading cause of death in our country, and it is really amongst the most dreaded words that anyone can ever hear. Everyone in this room and beyond this room has been affected by this disease in some way, shape or form, either themselves, someone in their family, a colleague, a child, a grandparent, an aunt, an uncle, a neighbor. So really, so many of us, I believe, we are all like one diagnosis away from something.

There are several bills, Mr. Chairman, that members have authored in the committee, and what I would urge you to do is to put together a compendium of these bills from both sides of the aisle and really see what we can move in this Congress. Sometimes bills don't have to be gigantic to really have an impact, especially in a specific area. So--

Mr. {Pallone.} Would the gentlewoman yield?

Ms. {Eshoo.} Certainly.

Mr. {Pallone.} Let me just mention that--I mean, not that we are making excuses but as you know, there was so much of the legislation that many of you have introduced on both sides of the aisle was either in the health care reform or impacted by the health care reform, and I think what we are going to do during the break, you know, the 2 weeks, is to try to sift through all that and see what is still relevant and not included in the bill, you know, once we go through reconciliation and then get back to all of you and say, okay, these are the things that we need to consider now between now and the end of the session.

Ms. {Eshoo.} That would really be wonderful, Mr. Chairman. Thank you.

And I just want to add how proud I am that in my Congressional district that we have a National Cancer Institute-designated cancer center at Stanford University and the work is really extraordinary, so the investments in this are amongst the best we can make as a society.

I look forward to hearing from the witnesses and thank all the people that have been advocates for years and years and years. Hang in there. We all need each other and we have got to get more done on this. Thank you.

[The prepared statement of Ms. Eshoo follows:]

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Mr. {Pallone.} I thank the gentlewoman.

The gentleman from Ohio, Mr. Space.

Mr. {Space.} Thank you, Mr. Chairman. I too waive my oral statement orally and submit it for the record.

[The prepared statement of Mr. Space follows:]

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Mr. {Pallone.} Thank you, and I think that concludes our opening statements. Did you want to say something?

Mr. {Shimkus.} Mr. Chairman, I ask unanimous consent that Congresswoman Judy Biggert be allowed to make an introduction of a former staffer on the second panel, and Judy.

Mr. {Pallone.} Without objection, so ordered.

Ms. {Biggert.} Thank you, Chairman Pallone, and Ranking Member Shimkus for giving me this opportunity to address the subcommittee. I am honored to introduce to the subcommittee today Kristin Fitzgerald, who not only is a constituent of mine from Naperville, Illinois, but she is also a valued former member of my staff and the staff of the Education and Workforce, now the Labor Committee. But it is not Kristin's expertise as an outstanding Congressional staff member that brings her to this subcommittee today. Rather, it is her experience in seeking treatment and a cure for a rare cancer that afflicted her late husband and dear friend of mine and Ranking Member Shimkus, Ray Fitzgerald. Kristin kept me, Mr. Shimkus and the rest of us on Capitol Hill informed via daily e-mails as to what was happening with her husband's treatment, and we felt like we were able to be with her every day during that difficult time. Unfortunately, just over a

year ago, Ray passed away from gastric cancer a mere six months after he was diagnosed.

After seeing firsthand the strengths and weaknesses of the cancer treatment system here in America, Kristin has used her knowledge of government to advocate for improvements in the dissemination of best practices at the NCI and other research facilities across the country. I believe that her ideas have the power to speed cancer research by better leveraging and coordinating our current efforts. Given the excellent work that she did in my staff, I have no doubt that she is up to the task. And with that, I would yield back.

Mr. {Pallone.} Thank you. Kristin is actually going to be on our second panel.

Before we go to our witnesses, though, let me just mention that our chairman, Chairman Waxman here is here, and if he would like to give an opening statement, we haven't begun with the witnesses yet.

The {Chairman.} Thank you very much, Mr. Chairman. I thank you for holding this hearing and giving us the opportunity to hear from the National Cancer Institute and other witnesses about the Institution's cancer research efforts.

Cancer is a complex disease. We know that genetic, environmental and other factors all contribute to an

individual's risk for developing cancer, so discovering cures and developing effective treatments are complex, difficult and expensive endeavors as well. We have made tremendous progress in reducing cancer deaths and new cancer cases due in large part to scientific advances over the last decade. However, cancer remains the second leading cause of death in this country and may soon overtake heart disease as the Nation's number one killer. One and a half million people are diagnosed with cancer each year. Eleven million people are cancer survivors. Cancer is particularly devastating for members of certain communities. Racial and ethnic minorities experience disproportionately high rates of cancer cases and death. All these individuals, their families and friends know all too well the tremendous physical, emotional and financial toll of this disease.

In the past 5 years, we have made strides in combating certain forms of cancer such as breast and cervical cancer. Other cancers pose new challenges. For example, while colorectal cancer rates have decreased overall, the number of people under 50 with this type of cancer is on the rise, and eight types of cancer, those that we often don't hear much about, account for half of all cancer deaths. I know these so-called deadly cancers are of particular interest to the chairman, Mr. Shimkus and other members of the subcommittee.

Today we have an opportunity to learn more about cancer research conducted and supported by the NCI to better understand where we are and where we hope to go in making advances to beat this terrible disease. This research spans the continuum of discoveries starting at the laboratory bench, then translating scientific breakthroughs into clinical application and finally testing for safety and efficacy to determine if new innovations really work at the patient's beside.

In every regard and throughout the world, NCI is considered the preeminent institution for biomedical research on cancer. The research funded by NCI will enable us to discover and ultimately deliver the best possible prevention, detection, diagnosis and treatment tools to all Americans. As we will hear, there is much to be excited about and, of course, there remains much work to do. I want to thank Dr. Barker and all of our witnesses for being here today, and I look forward to their testimony. Thank you.

[The prepared statement of Mr. Waxman follows:]

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Mr. {Pallone.} Thank you, Chairman Waxman.

Mr. Green, would you like to make an opening?

Mr. {Green.} Thank you, Mr. Chairman, and I would like to have my full statement in the record, but I can't get away without--I represent a district in Houston and we have there great NCI facilities at the University of Texas, Health Science Center, Baylor College of Medicine and of course the University of Texas M.D. Anderson Cancer Center. I thank NCI for what you are doing because I see it every day when I am home, so thank you.

I ask unanimous consent to place my full statement in the record.

[The prepared statement of Mr. Green follows:]

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Mr. {Pallone.} Without objection, so ordered. And all statements by members in full will be put in the record if they so desire.

Let me move to our first panel and only witness, who is Dr. Anna D. Barker, deputy director of the National Cancer Institute. Welcome, and thank you for being here today. I am not going to go through the drill. You know how we operate, so I recognize you for an opening statement.

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^STATEMENT OF ANNA D. BARKER, PH.D., DEPUTY DIRECTOR, NATIONAL CANCER INSTITUTE

} Ms. {Barker.} Thank you very much, Mr. Chairman and members of the subcommittee. It is my great pleasure to be here, and I want to thank you for the opportunity to testify today and for holding this hearing. The timing couldn't be more appropriate, I think.

I am the deputy director of the National Cancer Institute. I also have the singular pleasure actually of directing the strategic science initiatives for the Cancer Institute, and I will be talking about a couple of those today that I think you will find of some interest. It is really an exciting time in cancer research, as you heard earlier today. I would like to highlight a few of the advances in my testimony today and we can discuss them later, but I think we have unprecedented opportunities now to really increase progress against this disease that still tragically affects almost all of us in one way or another.

So an unprecedented convergence of advances in molecular biology and advanced technologies is beginning to transform our understanding of the mechanisms of cancer, and that is incredibly important. Cancer is a disease of changes in our

genes, so if I don't deliver any other message today, maybe we can take that away. Some of these genes are inherited. You can't choose your parents. But some of them, actually most of them are actually acquired as a consequence of the way we lives our lives. As you will hear, we are systematically identifying these genomic changes in cancer, which is allowing us to finally identify the molecular basis of subclasses of cancer and develop targeted interventions. That is quite a step.

These discoveries really represent a paradigm shift. It will take time but knowing the molecular makeup of a cancer will allow a patient to be treated according to their tumor's signature. As the cost of sequencing the human genome continues to fall, and it is falling almost daily, and bioinformatics facilitates the availability of an electronic medical record that captures all of a patient's data in this next decade, and beyond, we are going to transform the way cancer is diagnosed, treated and prevented.

NCI is leading this revolution through programs that range from studies that define specific changes in the genomes of cancer patients to nanotechnology-based diagnostics that can detect miniscule amounts of cancer in a patient. I would like to tell you a little bit about a few of these programs in this limited time that I have, but I

481 think the programs I am going to tell you about will change
482 our definition of cancer, allow us to better understand why
483 certain cancers have poor outcomes and provide new approaches
484 to control all cancers.
485 Led by Dr. Francis Collins and myself in 2005, the NCI
486 and the NHGRI, which is the National Human Genome Research
487 Institute, launched a groundbreaking collaboration called The
488 Cancer Genome Atlas--I will refer to it from now as TCGA,
489 which you should remember--to ultimately identify and catalog
490 all of the relevant genomic changes in most types of cancer.
491 This is an enormous undertaking. The Cancer Genome Atlas is
492 one of those paradigm-shifting programs that I mentioned
493 earlier. It employs state-of-the-art genomic
494 characterization and sequencing technologies, engages a
495 network of multidisciplinary centers, which is actually
496 composed of tens of institutions and hundreds of experts in
497 genomics in cancer biology and deposits all of the data in a
498 public database. TCGA is the largest and most comprehensive
499 analysis of the molecular basis of cancer ever undertaken and
500 the project has already faced and overcome a large number of
501 technical and scientific challenges in the first three years.
502 We launched TCGA with a study of glioblastoma, which is
503 the most prevalent human brain tumor in adults, and ovarian
504 cancer and squamous cell cancer of the lung had followed soon

thereafter. In 2008, the first major results of the TCGA pilot program produced a map of these three key pathways that are disrupted in GBM and defined the four specific molecular subtypes of this cancer, paving the way for identifying the right patient for the right drug. The availability of a highest-quality, multidimensional data set on a statistically valid set of high-quality samples is bringing new investigators and teams forward to study GBM in large numbers. This is one of the goals of TCGA, so we are bringing tons of people to the table to study this cancer.

We are about to do the same thing for high-grade serous ovarian cancer, which is responsible for most ovarian cancer and a major contributor to the overall 5-year survival rate of only 31 percent. These data are being finalized for publication. I haven't talked to anybody about the data but I am going to tell you a few things that no one else will know. First, at one level, ovarian cancer looks quite different from GBM at the genomic level but in another way it looks quite similar. Ovarian cancer is a study of genome instability with a highly disrupted genome. It is a disease of copy number change, which actually means a disrupted genome. This instability is likely driven by nearly wholesale changes in only three genes. There are three distinct molecular subtypes of ovarian cancer confirmed at

multiple levels of the genome. The distinct pathways disrupted in ovarian cancer where there are signatures can predict survival duration. That is quite a finding. Overall, the tumor is driven by defects in genes that are responsible for repairing damaged DNA, and there are a number of other rare genes that may represent new targets for drug development. The data is going to open a whole range of new windows of exploration for diagnosis and treatment of ovarian cancer that I predict will change the future for ovarian cancer patients hopefully on an accelerated schedule.

The value of TCGA will ultimately be measured in many advances but perhaps one of the most striking is the value of the integration and analysis of multidimensional data about the many cancers it will study. Using ARRA funds, we are currently expanding the scope of TCGA to explore 20 additional cancers over the next 5 years, 10 in the next 2 years. Many of these studies will include the rare and deadly cancers that you will all be asking me about later.

One additional comment I would like to make is that one of the rate-limiting steps in TCGA has been the availability of rare cancer samples and very high-quality cancer samples, and we are hoping to work with the advocacy community to fix that problem. Achieving high-quality biospecimens for the country is a major challenge. This is the foundation for

personalized cancer medicine. It is also a problem in terms of the way standard of care is practiced in this country and it is also a problem with most of the tumor samples in the country where only about 30 percent of those samples are available and can be used in a high-quality study like TCGA. NCI has launched something called the cancer Human Biobank to deal with that issue, so we are going to have a national biobank.

The other program that I wanted to highlight just for the last minute is basically what we are doing in nanotechnology. Nanotechnology, as you know, is allowing us to measure things at levels we only dreamed about a few years at 1 to 100 nanometers, roughly the size of a water molecule to the size of a bacterium. Recently, we have been able to show with nanotechnology that you can measure in this particular case cancer changes roughly six times more sensitively than some of the diagnostic tests that we are using today. Northwestern University reported just 2 weeks ago using a barcode assay in DNA, they can actually detect prostate cancer at a level that is unheard of, and we believe going forward we will be able to use that kind of information to detect these cancers much, much earlier.

Another recent breakthrough that was only published yesterday from the Nanotechnology Alliance for Cancer, which

was started by NCI 5 years ago, we are now able to know that there is a piece of the genome actually called RNAI that actually blocks the expression of certain genes. We haven't been able to deliver that. It gets actually degraded in the body. We had a nanotechnology investigator from California, actually from Cal Tech, report just yesterday that they have been able to deliver this to patients and it is going into phase II trials. Again, this is another breakthrough from the nanotechnology program that NCI started about 5 years ago.

At NCI, we are really proud of the progress we are making in these advanced technology programs. We are excited by the opportunities that lie ahead and challenged by the daunting amount of work that we have yet to do. We are dedicated to achieving a future where the shadow of cancer is removed from our lives and those of our children and our grandchildren. This increasingly seems to me like an achievable mission and a vision for every American that we can achieve hopefully in this next decade. NCI and NIH and are committed to moving us all forward toward this future, and I have never been more excited about believing that we will achieve this future for every patient, for every family and everyone touched by cancer, including my own. I have lost all of my family to cancer. I have been in this field

for my entire career. I lost my grandmother to pancreatic cancer, two additional relatives to pancreatic cancer, my mother to breast cancer, my sister to breast cancer and my father to lung cancer.

Thank you.

[The prepared statement of Dr. Barker follows:]

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Mr. {Pallone.} Thank you, Dr. Barker. We are going to take questions from the panel beginning with me, and I have to say that as much as I am tired and I know many of us are from the long weekend, I am also very excited by your testimony. You mentioned nanotechnology, which I think is so important for the future. We just had a--well, not just but within the year or so I went to an all-day conference at Rutgers on nanotechnology and some of the things that were really interesting that they were doing, and when you were talking about your relatives, I feel the same way, you know, my mother with pancreatic cancer, father-in-law with brain cancer. These deadly cancers are just around us, you know.

When I went to Johns Hopkins with my mom, I was surprised to find out how much of a hereditary factor there was. Now, I don't think it was that significant. I think they said 10 or 11 percent that they could say were hereditary, which isn't really that much, but the first day we arrived and they were looking at my mom, they took myself and my brother into a separate room and say by the way, there is a certain hereditary factor here, and they put us in some kind of a genetic bank or something to get back to us if there are breakthroughs because of the genetic factor, and I was of course--the first question they asked do you have a

history of this in your family, and my mother actually was adopted so we absolutely no information to relate to them other than her. But I know that all these things you mentioned are so important, really. I can't stress that enough.

I mentioned in the opening about this genome atlas that I guess examines genetic material of various tumors and looks into gene mutations and different things genetically, and I know that you have some new findings in that respect with regard to ovarian cancer, but this atlas I guess from what I understand gets updated and may be expanded, I suppose, to include some of these other deadly cancers, so I wanted to ask you, you said it is going to be expanded to include 20 additional forms of cancer over the next 5 years and NCI will look at half of these within the next 2 years. So tell me, what is the basis for selecting the 20 additional cancers that you research and what is the timeline for that selection? How is that process gone about?

Ms. {Barker.} It is an excellent question. It turns out that as I said, the biggest issue we have with doing these very sophisticated studies is the availability of the samples. So as you can imagine, we are looking everywhere for samples, and to give you some feel for how difficult this was for GBM, glioblastoma, which is this adult brain tumor we

did first, we had to look everywhere in the United States and outside the United States to get enough samples to actually do that study. It turns out that only about 30 percent of those samples qualify, and that is not a bad number for most of the samples in the country right now. Why is that? Well, people collected these samples for many years. They weren't thinking a lot about when they collected the samples the advanced technologies we would be using today. So in terms of selecting cancers for the atlas, the first priority is, are the samples there, are they available, and so we are doing very well. We are moving ahead on lung cancer. We are just introducing kidney cancer into The Cancer Genome Atlas, already have actually. Colon cancer is already being introduced into the atlas. We have cervical cancer and potentially gastric cancer to come into the atlas. Now, the latter one obviously is a rare tumor and so we are having to look in many, many areas to find these samples. By and large, or at least as we move forward, we think that we will also be able to prospectively collect samples and that will be driven mostly by which tumors are prevalent and which ones we can actually lay our hands on in the most rapid fashion, but we can collect tumors prospectively now and actually make sure that they meet our very stringent criteria. So going forward, we are going to use a combination of retrospective

samples and prospective samples.

But it turns out to be the biggest barrier we have. I mean, who would have guessed going into this that this what most scientists would have considered a trivial issue is non-trivial and it is going to be actually the basis for personalized medicine overall so as a country we have to face up to the fact that we have to start treating our patient samples as well as we treat our patients, if not better, because they are going to actually define what personalized cancer medicine can be. So at NCI we started a lot of initiatives including best practices for how you collect samples and store them and actually what the stewardship is going to be of those samples. We think it is critically important.

Mr. {Pallone.} I would just ask you, I know that I and several members, maybe all the members of the committee, are interested in tracking any progress that you make on this cancer genome atlas, and keep us abreast of your efforts as you go along because this is of interest to me and to all of us. We appreciate it.

The gentleman from Illinois, Mr. Shimkus.

Mr. {Shimkus.} Thank you, Mr. Chairman.

Dr. Barker, welcome and we are glad to have you here. The budget request this year is $5.26 billion. It is a $163

million increase over fiscal year 2010. Add to that $1.26 billion provided by the stimulus bill. How do you go about apportioning out--we as members have disease groups all the time that descend upon us, and it is a sad kind of a food fight. So how do you apportion research dollars to cancer, the various cancers?

Ms. {Barker.} With great difficulty.

Mr. {Shimkus.} Like we do, I think.

Ms. {Barker.} I think at the last count there were a little over 400 survivors' groups, I think, relative to cancer of one sort or another, and so what we try to do is to look at what is really promising in terms of what is going to enable cancer research that will actually be translatable to patients and backing into that what is really going to inform the biological space that will allow that to happen. I mean, if you think about what is really required for cancer, it is to understand the mechanisms that actually drive this disease and that is understanding the biology, and that has taken some time and we have built a really strong base for that. So what we try to do at NCI is obviously about half of our portfolio is driven by what we call individual investigator-initiated research, which is the strongest part of what we still do in science today. It is innovative. It is driven by in innovation and individuals' ideas. The rest of our

portfolio is dedicated to things like our cancer centers, our specialized programs of research excellence, our clinical trials infrastructure, et cetera. So cancer is a very, very big problem in the country so there is a fair amount of infrastructure that we have established in the early 1970s, actually the early 1960s.

The other thing we try to do is the area that I lead up the NCI through the Center of Scientific Initiatives, we try to focus on areas that we think are enormously promising like cancer genomics or nanotechnology or proteomics, the biospecimen issue, cancer bioinformatics. These are all things that we have tried to focus on over the last several years.

Mr. {Shimkus.} If I can, because I have only got a couple more questions that I want to ask, but I appreciate that. But I want to follow up on--

Ms. {Barker.} So balance, I guess, is my answer.

Mr. {Shimkus.} I know, I expected not an easy answer of how you do it.

In the appropriations bills of last year, we addressed both sides of the Hill. We encouraged NCI to put a high priority on GI cancers in people age 40 and under and for NCI to consider developing an interconnected gastrointestinal cancer biorepository. Where are we at on that, and can you

give us any response as far as what progress has been made, what factors are you considering to determine if a GI repository should be developed? What else can we do? Obviously that is a particular focus of this hearing and my interest.

Ms. {Barker.} I think the GI spores are really well underway and they are collecting their samples and so we will have samples from this specific cancer, so I think that is going alone fine. The other thing that we have done just recently is, we held a meeting just last week on infectious agents in cancer, and as you know, gastric cancer especially is related to H. pylori, an infestation of a bacterium in the gut, but not all stomach cancer is caused by H. pylori, and you heard about one of those today, I am guessing. So we are trying to also now investigate other areas that are related to intestinal cancers other than just the kinds of normal things we have been looking at over the years, specifically, infectious agents.

Mr. {Shimkus.} What about the cancer Human Biobank, which seems very promising? Can you talk about that?

Ms. {Barker.} Yes. We had hoped to--we were planning on launching that probably next year, but with the aid of the ARRA funding, we were able to launch it in 2009 with about $60 million. So it underway. We expect it to be well

underway in the next 3 years. Certainly by the end of the ARRA period we will have it well underway and samples are already beginning to flow in. The infrastructure is being created. So thanks to the ARRA funds, we were able to get it underway at least a year earlier than we would have been able to do it before.

Mr. {Shimkus.} And I appreciate your quick answers. I still have 20 seconds left.

There are some difficult biological materials to obtain in this process. Can you identify some of those?

Ms. {Barker.} Well, any of the rare tumors basically. I mean, the rare tumors are really hard to get. Sometimes it is because of standard of care. Sometimes it is because people hang on to their samples; they are very precious and they don't want to share them. So I would say any time that we can encourage and I think really engage the advocacy groups to help us to collect these samples, that is where we should be focusing.

Mr. {Shimkus.} Thank you, Mr. Chairman.

Mr. {Pallone.} Our vice chair, Ms. Capps.

Mrs. {Capps.} Thank you.

I found myself, Dr. Barker, getting goose bumps while you were giving your testimony. I think it is very stunning what you were telling us, and I would like to have you use my

time to talk more. The whole notion of personalized medicine is kind of floating around there. You are kind of pinpointing it so we can know, but you mentioned Cancer Genome Atlas, and is that what Mr. Shimkus asked you about?

Ms. {Barker.} That is what the chairman is talking about.

Mrs. {Capps.} Yes, and the Human Biobank would be part of that atlas?

Ms. {Barker.} Separate ideas and separate concepts and separate initiatives but very much related to each other because the cancer Human Biobank will collect these samples and make them available to The Cancer Genome Atlas.

Mrs. {Capps.} And then I guess the part that is so intriguing to me, you could talk on and on, hours, I suppose, just about that--

Ms. {Barker.} And I am Irish, so you don't want to do that.

Mrs. {Capps.} But maybe another time. I have a feeling we are just getting into this, and I feel myself wanting very much to be educated.

I want to try something on you because there is a--we found that there is a piece of our health reform language that is about research on cancer, and the part that intrigues me is the Cures Action Network, another new initiative. I am

just quoting from the language of the legislation. ``New initiative created in the legislation, an effort to help translate promising discoveries into cures with an emphasis on priority health issues where incentives for development are inadequate guided by''--this is all to be--``guided by a board of scientific experts and venture capitalists, individuals who have experience identifying promising projects. These experts are teamed with advocates who can represent the needs of patients. How would you see that what you do there? I sort of call that pure research, if you will, and then also with the atlas and those samples, how can these results, your results, be translated more quickly to treatment and cures?

Ms. {Barker.} So I think it is end-to-end solution. I mean, basically you are starting with the samples. You are going through The Cancer Genome Atlas identifying all of these pathways that are disrupted. It allows you now to sort of attack that valley of death where things get lost and we don't have a real opportunity to take things to the next step. I think it is a very exciting idea.

Mrs. {Capps.} Will you be doing that or do you see yourself collaborating? I don't mean you personally but--

Ms. {Barker.} Probably both. We do a lot in translational research already but this allows actually--if I

understand it correctly, it allows for more direct relations and public-private partnerships to occur, which is something that is missing now in terms of really moving these new treatments into patients. I think that is long overdue and I think we can make good use of both the mechanisms and obviously the resources.

Mrs. {Capps.} So we need to stay in touch with you. I am suggesting this to my chairman at the same time. This is a work in progress, both where you are and also this is a brand-new piece of legislation, to find out those ways that those connections should be made and using the advocacy groups because they are so useful to all of us.

Ms. {Barker.} Right.

Mrs. {Capps.} And then connecting to the private sector.

Ms. {Barker.} Once you know which of these pathways is disrupted and which of these pathways are driving a specific cancer, then you are going to have to be able to make a new intervention or a drug, and The Cancer Genome Atlas is already sending the private sector in new direction to discover new drugs. We are already seeing changes in the way that they are actually doing business. So the government is actually having a lot to do with sort of redirecting the way discovery is going to occur in the future.

Mrs. {Capps.} Again, it is very exciting. I have 48 seconds left that is yours. What else would you like to tell us in that very short time?

Ms. {Barker.} Well, you can't say much in these prepared statements so the couple things I would say is that The Cancer Genome Atlas is an example of something that is really changing science. I mean, it really is bringing hundreds of people together to look at a disease as complex as cancer and integrate all the data and make it available.

Mrs. {Capps.} Let me just interrupt. Say there is someone who walks into a doctor's office and they take a biopsy and it comes back, and that is the point that I think we all can relate to. How does what you are talking about connect there in any way?

Ms. {Barker.} So in a few years--when we started The Cancer Genome Atlas it was a couple hundred million dollars to sequence a cancer genome. It is now down to tens of thousands of dollars, and I would predict in as little as 5 years it is going to be down to less than $5,000. You get your genome sequenced, and we are going to know what the disruptions are and we are going to know what subclass of cancer that you have and you will get the right drug. You will not be treated with a generic sort of treatment. You will get the right drug for your subclass.

Mrs. {Capps.} And you will have it in the bank, or someplace it will be?

Ms. {Barker.} Well, if we can move ahead quickly on the things that you just talked about in terms of developing these new treatments, absolutely. So I think it is going to change the way medicine is practiced completely.

Mrs. {Capps.} Stunning. That is all I can say. We have to do this more, Mr. Chairman. Thank you.

Mr. {Pallone.} I realize that this is a subject of great interest and we will look into possibly doing additional hearings. We only have 6 months left, though, before the end of the session.

The ranking member, the gentleman from Texas, Mr. Barton.

Mr. {Barton.} Thank you, Mr. Chairman.

Thank you, Doctor, for appearing. Dr. Andy von Eschenbach is not only a professional acquaintance but a personal friend and has helped me in treatment decisions for members of my family, so he is somebody that I have a lot of respect for. He has told me that with the proper approach and proper funding, we could actually find a cure for cancer in the next 15 years. Do you share that view?

Ms. {Barker.} I think it depends on how we define ``cure.'' I think what will happen in this field, and Andy

and I have discussed this on many occasions, is we are going to learn enough about these cancers to actually be able to treat them and have people live normal lives, and if you call that a cure, then that is a cure, but I think if you can stop the growth of a cancer, and let us just say even the cancer comes back, much as you see with AIDS patients, if you now can go in with another treatment that is equally effective and someone gets another 10 years, let us say, which is what is happening with breast cancer patients today, for example, then you are going to live out your life normally and die from something else. So that is the road we are on with cancer. Cancer is an extraordinarily complex disease, probably the most complex disease we have ever undertaken, but we are going to understand it well enough to be able to control the pieces that need to be controlled on a time frame that will allow you, I think, to live a fairly normal life. So I think that is the future.

Mr. {Barton.} Now, I don't have the article in front of me but several months ago I believe Newsweek had a cover story about the war against cancer and was the wrong battle being fought. The article was not necessarily negative but it did raise some questions. Are you familiar with that article?

Ms. {Barker.} Yes.

Mr. {Barton.} What is your general view of that? It implied to me that we are spending a lot of money and kind of doing things the conventional way, which is somewhat contrary to what you just discussed with Congresswoman Capps.

Ms. {Barker.} Well, those that know me know that I do very little in a conventional way. I mean, most of the programs that we started at NCI are pretty unconventional, whether it is nanotechnology or The Cancer Genome Atlas or some of the other things we have done. You know, this happens three or four times a year that we have a national story that says, you know, why aren't we winning the war on cancer, and, you know, I think it varies from time to time as to what the issues are, but I think we do have to look at these diseases differently. If we can actually balance the amount of individual investigator-initiated research with some of these larger programs, I think we will proceed faster. So I think we have to come up with sort of piece coexistence of programs that enable everybody in individual investigator-initiated grants.

Mr. {Barton.} But you do have a mechanism with NCI to review that type of--

Ms. {Barker.} Yes.

Mr. {Barton.} So there are people thinking about different ways to do things?

Ms. {Barker.} Yes. I think it is the biggest change that we are going to have in cancer research and ultimately in the way products are developed for cancer patients. The one thing I didn't say but maybe it is obvious to everybody on the subcommittee is that cancer is digital, it is knowable, it is information. Think about it. I mean, you know, you pick up this device or another now and it is turning over every 5 years or it seems like every 2 months you are getting a new device. Well, once we digitize cancer, which is what we are doing with The Cancer Genome Atlas, going back to the Human Genome Project, that is what the Human Genome Project taught us, that DNA is digital, so as you begin to learn the information about cancer, you are going to be able to move much more rapidly, I think, and I think if cancer is knowable and we can decipher all the genes that cause these cancers and make them available to everybody, that is going to move the field exponentially.

Mr. {Barton.} Now, one of the things that we did in the NIH Reauthorization Act several years ago was create a common fund that requires a certain amount of money each year to go into this fund and requires those that wish to take advantage of grants from that fund to work across different areas of NIH. That fund has been in existence now I believe for 2 years, maybe 3. Is that type of approach something that

would tend to help the approaches that you are focusing on at NCI?

Ms. {Barker.} They are very similar, and some of them have actually come from the common fund or enabled the common fund as many of the NIH institutes actually work in this way. I think the common fund is a great idea. I know Dr. Collins is now looking for new ideas for the common fund, so yes, they are very complementary and I really commend you for the common fund and the idea. It has been very, very helpful.

Mr. {Barton.} And my last question, we are bombarded every year on this committee with requests from advocacy groups for special bills for specific diseases and specific cancers, and each group, whether it is the breast cancer group or the cervical cancer group or the prostate cancer group or the autism group or the Alzheimer's group or you name it, the heart group, theirs is always in their minds the priority that we should fund. What is your advice to the Congress on how we should handle those kinds of bills?

Ms. {Barker.} So we see the same groups, and I think increasingly I believe that understanding the biological space or understanding the biology that drives cancer and other diseases is going to be critical to everybody. So I think that what we do--and we are learning so much now from The Cancer Genome Atlas that says that, for example, GBM, the

pathways that are disrupted in GBM are going to look like the same pathways only a bit different in terms of the quantity of the genes and the exact numbers of genes that are actually disrupted in ovarian cancer so there are going to be some interesting overlaps here that are going to tie these cancers together. So I would encourage us all to begin to unravel that mystery that is cancer as opposed to, you know, what is prostate cancer, what is breast cancer, what is this cancer, what is that cancer. I think that is all going to converge and it is starting to converge now. So we need to work together to fill in the biological space and find out what drives cancer, and I believe it is going to help all these diseases.

Mr. {Shimkus.} Will the gentleman yield?

Mr. {Barton.} Yes, I would be happy to yield.

Mr. {Shimkus.} Just to follow up. Thank you, Dr. Barker. In talking about again the cancer Human Biobank, how do we envision researchers across the board having access and using that? It is kind of tied to the same question based upon research. Because a lot of the advocacy groups are also doing research that I am not sure how--if we are getting access to that information or how that all works out. Can you in the last minute of--

Ms. {Barker.} So in the last minute--it is a complex

issue. The cancer biobank is just getting underway. The Human Biobank is just getting underway. But what we want to do is, we will have to prioritize access because some of the samples will be quite precious. So what we envision is having a board for the biobank that will actually prioritize requests and make samples available and information available on a priority basis but we generally will also offer services to investigators who are just looking for or need samples and so I think both of those will be possible in the biobank.

Mr. {Shimkus.} And how do we incentivize people? We will have testimony in the next panel of someone with a rare cancer who when they had the availability there was no place to go. How do we encourage a place to go?

Ms. {Barker.} For?

Mr. {Shimkus.} I am not a doctor, but the tissues from this stuff. Some of these rare diseases, they are rare. It happens, it is gone and then you have no place to get the tissue to go to.

Ms. {Barker.} Well, I have proactively--for The Cancer Genome Atlas, the first three choices were rare tumors basically: squamous cell carcinoma of the lung, ovarian cancer and GBM, GBM being the toughest. We spend a lot of time thinking about and working on these highly lethal tumors, and we will do more. The Cancer Genome Atlas will

allow us now to look at these tumors. We are going to need help with getting the samples, and this is where the advocacy groups can really play a role, and I spoke just recently with the Deadly Cancer Coalition and we are working with several of those groups now to get those samples into The Cancer Genome Atlas. So I think it is working.

Mr. {Barton.} Thank you, Mr. Chairman.

Mr. {Pallone.} Thank you.

The gentlewoman from the Virgin Islands, Ms. Christensen.

Mrs. {Christensen.} Thank you, Mr. Chairman. Thank you, Dr. Barker.

It is very exciting. It was very exciting to read to and to listen to your testimony today. You focus a lot on of course the genomics and the molecular biology, but when you talk about bringing all of the experts together and all the data together, does that also include experts on environmental and psychosocial? Does that come into the discussion as well?

Ms. {Barker.} Yes, because we are collecting data. I mean, I didn't have time to mention but all the samples we are using are actually from patients that are extraordinarily well characterized. They have to be to get into The Cancer Genome Atlas. So we have survival data on these patients,

exposure data, et cetera. So as we go through these processes and learn more and more about these cancers, we will be able to begin to dissect out some of the questions relative to environmental exposures. I know Dr. Collins is planning a larger initiative in that regard to look at longitudinal data in terms of looking specifically at lifetime exposures in patients. We don't have that capability right now.

Mrs. {Christensen.} Thank you. A Dr. Foege, I guess is how that name is pronounced at CDC, is quoted is saying, ``The challenge to genomics is to overcome the inequitable allocation of benefits, the tragedy that would befall us if we made the promise of genetics only for those who could afford it and not for all of society.'' So how do we incorporate population-level considerations of personalized cancer medicine and ensure that the emphasis on molecularly targeted therapies won't exacerbate the health disparities?

Ms. {Barker.} I have lots of friends who always ask me this question--Harold Friedman from New York, who was at the NCI and actually founded our disparities program. I honestly think that this is going to do a lot to remove many of those barriers because one thing we are finding actually is that early on I think people assumed that maybe if you take the African American population, for example, that their cancers

look the same as other cancers, and in fact, it is likely not to be the case. So we are studying these cancers now and we have cohorts of these cancers where we will be able to determine if there are differences, if there are inherited differences and if there are population differences. We are also working across borders with several countries. Almost all the countries now have actually--The Cancer Genome Atlas has become very popular. It is being cloned in lots of countries now. There is a meeting going on in Spain today that I was supposed to be at, but the United States, we are actually providing all these countries with the construct for how we are doing this. So there are going to be lots and lots of data on many countries including Africa where we will be able to sort out a lot of these differences. So I think actually this could reduce the digital divide and I think it will because I think we are going to know enough to do what is right for all these populations, not just for some.

Mrs. {Christensen.} And are you doing anything, any specific research on the more aggressive forms of breast cancer that black women are disproportionately likely to get? I noticed that in your plan you say you are using ARRA money to look at health disparities and really target these kinds of issues.

Ms. {Barker.} Right. So you are talking primarily

about triple-negative breast cancer, which is a devastating cancer and it is quite high in African American women and quite devastating, and we have a number of programs in the NCI looking at that. We just launched a new program which I don't have time to talk about last week actually called the I-SPY 2 trial which is actually a program to look at breast cancer in the neoadjuvant setting. Patients are going to have surgery. Many of those patients will be triple-negative breast cancer patients but the idea is to use an adaptive trial and test a large number of agents which we have not been able to do before and move drugs through very quickly. So I think we have got a lot of attention on that disease right now.

Mrs. {Christensen.} Great. We could probably look that up on your website?

Ms. {Barker.} Yes.

Mrs. {Christensen.} One last question. I notice that you have a center to reduce cancer health disparities at the NCI. I would like to just know how do you relate and interact with the National Center for Minority Health and Health Disparities research.

Ms. {Barker.} Very close interactions, and I think our center for reducing health disparities is a real flagship for all of the initiatives that are ongoing around cancer and

disparities, and everything from our centers, you know, where we are actually training and bringing in new investigators, minority investigators especially, to some of the special research programs. It is really quite a success.

Mrs. {Christensen.} Thank you.

Thank you, Mr. Chairman.

Mr. {Pallone.} The gentleman from Indiana is recognized for 8 minutes. Mr. Buyer.

Mr. {Buyer.} I thank the gentleman.

Ma'am, when you were holding up your cell phone, I couldn't help but sense that as you talked about the genome and how fast our discoveries are moving, I am going to ask a question. I don't know the answer to this but I am going to do a systems analytical, and this would be our delivery systems. Sometimes our delivery systems can be caught in time. It is logistics, it is who is doing what in the preparation of what you described as that proper drug. So if you take yourself back actually maybe 15 years ago, some of the larger pharmaceutical companies did some discoveries and they held the drugs and they realized that they couldn't keep up and some would then spin them off either into the compound pharmacies or some nuclear pharmacies and they would be responsive to some cancer hospital or clinic or particular doctor, and so we have a unique delivery system on how that

proper mix is getting there. Is that delivery system keeping pace in order for us to do that specialized proper care as you envision?

Ms. {Barker.} Well, that is a tough question.

Mr. {Buyer.} I don't know the answer to it either.

Ms. {Barker.} Well, I think I do know the answer. I mean, I think the answer is, as of now I think we are keeping pace pretty well because the targeted drugs we are using in cancer research today, drugs like Gleevec and Avastin, are getting to patients. I think the bigger question is, when we have hundreds of these kinds of drugs and you are going to be hard-pressed to know everything there is about every one of these drugs, will people keep pace then. I think that information is going to change and the amount of information available is going to change at a pace that will allow people to keep up. But I think delivery is going to be the major challenge. I don't disagree with that. I think it is a huge systems challenge.

Mr. {Buyer.} I asked that question from a systems analytical approach. We have a regulatory--all these regulations that are in place. Take, for example, a doctor that--you said the personalized sampling increasing personalized care. So when the doctor now knows what my patient's needs and requirements are, sends off to someone

for a particular proper drug mix and it is then placed into the delivery system whether it is FedEx or UPS. Now it comes under some other regulatory schematic and maybe it is held in FedEx, it is brought in overnight and it is now held in a different place because of the regs and it has a time--sensitive in time. And now it may sit there for 2 days, and by the time doc gets it, how stale is the mix with regard to toxicity? You know what I am saying? I look at our system here and you say okay, the more we personalize, the better care we can get, but are we doing what we need to do because by the time that proper mix gets, is it going to do what the doc wants. This is my question.

Ms. {Barker.} Well, I am not funded for FedEx but I can tell you right now that the delivery of drugs in this country is a very high priority for the pharmaceutical companies that actually send them to physicians, and the delivery thereof is highly monitored by physicians because everybody knows that many of these drugs are actually not terribly stable. They have to be kept at certain temperatures, et cetera. I don't think we see that problem very often but to your point, as you have more and more of these, it could become more of an issue. So it is a systems problem.

Mr. {Buyer.} That is why I am asking the question. If this is where we are going, when you say what is our over-

the-horizon vision, will our delivery system match your vision. Maybe I should--

Ms. {Barker.} No, and I think--in oncology we have been working on that for many years and I think, you know, because we do have an oncology community, especially a community of physicians that are very, very good at keeping track of the information. I think it will morph according but it is going to be a huge challenge, I mean, for all diseases, not just cancer actually.

Mr. {Buyer.} I yield to Mr. Shimkus. Are you good? I yield back my time. Thank you.

Ms. {Barker.} You are welcome.

Mr. {Pallone.} Thank you. Recognize the gentlewoman from Florida, Ms. Castor, for 8 minutes.

Ms. {Castor.} Thank you, Chairman Pallone, very much.

Dr. Barker and everyone at the National Cancer Institute, thank you very much for all that you are doing on cancer research and that vital--it is fundamental to American families and the struggles they have every day with cancer, and as my colleague said, there is just no one that has been unaffected.

I am particularly enthused about your focus on genomics. I represent the Tampa Bay area that is home to the Moffitt Cancer Center, and they are really at the forefront of the

national genomics project and have been educating me over the past few years, and let me tell you, even the Recovery Act money now, the NCI money, the Recovery Act that has gone to even greater research dollars and jobs, kind of high-wage jobs we want in our community and this new emphasis on genomics, and we also get support through the defense bill to even bolster the NCI funding. Moffitt launched their database in 1999 and they have been gathering that genomic data, the genetic profiles and the clinical history data for each enrolled patient, and I guess the next big step was to reach out to other researchers and other hospitals and begin that important partnership on the biorepository. So we are spreading out across Florida through the Moffitt, and I would like you to expand a little bit more on that data collection and the sample collection. I know the Moffitt, we have got 50,000 cancer patients so far have consented to have their clinical data and molecular profiles added to the database and that is going to be accessible to physicians, researchers and the patient themselves. They call it the total cancer care database that then flows into the personalized treatment that you are talking about.

But could you drill down farther on the details of collection and the challenges that we are going to face? You did mention in passing the protocols, ensuring that the

sample meets your standards. Talk a little bit about that in the data collection.

Ms. {Barker.} So first of all, I just have to say that Dr. Bill Dalton at the Moffitt Center is one of the prime examples of a state that has actually put their whole state ahead. I think of the curve here. It is an amazing amount of work that they have done and they have actually taken a lot from The Cancer Genome Atlas directly and implemented it in Florida, a very commendable effort.

In terms of some of the specifics, I mean, we have established at the NCI a set of best practices guidelines which I think have enormous merit for all investigators to be held accountable to, and so we are working on that, but I think in terms of the specimens themselves, they are very prescribed SOPs, or standard operating procedures, for how long in the operating room, you know, when it goes into storage, how it stored, how you access it, the kind of bioinformatics platforms that you need to keep track of the samples, the consent that goes with the samples, and in this era of genomics they are quite different consents for patients than they were before. So there is an enormous amount of information. Moffitt has all of that, and they have been using our standard operating procedures now for a couple of years.

Ms. {Castor.} So you have got how many research institutes that are part of genomics data gathering right now?

Ms. {Barker.} Well, there are literally hundreds of those, but for The Cancer Genome Atlas, there are probably 20 different institutions that are contributing.

Ms. {Castor.} And then is it their responsibility to use your framework and the SOPS--

Ms. {Barker.} Yes.

Ms. {Castor.} --to continue the outreach to gather those samples?

Ms. {Barker.} That is correct, and what you want is a standardized approach so we are all talking about the same things when we get to experimentation. Now, I thought you were going to ask a different question, and that is--

Ms. {Castor.} What did you think I was going to ask?

Ms. {Barker.} That is that there is something about these samples--we are actually doing some research on what causes changes in samples. We don't know. I mean, patients undergo anesthesia, all kinds of things in the OR. We don't know what impact that has. We have undertaken some research at NCI to try to figure that out. It is an interesting problem.

Ms. {Castor.} How often does that occur? Is that

standard, happening throughout all the samples?

Ms. {Barker.} Well, it is actually--we have just undertaken that research in the last 2 years. No one has ever asked the question before. No one has ever said, what is the impact of anesthesia on a cancer sample, I mean, until I hired a pathologist to come to NCI, who I have known for a very long time, and the first question she asked me was, how do you know the anesthesia patients get is not actually responsible for the biomarkers you are measuring versus the biology itself. Nobody ever asked that question before. So we are doing research now to answer that question but it is a very important question, along with several other questions that we are trying to answer, so it is an interesting set of questions driven now by personalized cancer medicine because we want to know what those samples are actually telling us about the biology.

Ms. {Castor.} And as you build this digitized database, I guess it is the molecular footprint for each of these cancers?

Ms. {Barker.} Right.

Ms. {Castor.} And then you have control factors based on all sorts of considerations. Can you state again in plain language what that means? Maybe go back to the latest ovarian cancer findings, what that means to a patient now and

in the future.

Ms. {Barker.} So what that will mean is that take ovarian cancer. We have identified three subclasses of ovarian cancer, very clear molecular subclasses. So we are going to know which drugs work on which subclasses. We already have survival data that says these drugs predict survival and these subclasses, at least two of the subclasses, so you are going to know as a patient what you should get, and you are also going to know as a physician whether or not anyone should get any drug basically. You know, right now we generically treat everybody with the same drug. If you have ovarian cancer, you either get a platinum-based drug or you get Taxol, and you may benefit from one, you might benefit from both, you may benefit from neither. So now we are going to be able to tell you which of these you are going to benefit from and the physician will have some idea about the expected longevity. As we go forward, I think you are going to see more and better cancer therapeutics for those specific subclasses, and that is the whole goal of The Cancer Genome Atlas. So patients can benefit very quickly by actually being put on the right drugs, I mean, going into the right clinical trials, putting patients in the right trials and then ultimately treating patients with the right drugs.

Ms. {Castor.} And they benefit by submitting their

samples?

Ms. {Barker.} Yes, and increasingly every patient coming in for any diagnosis of cancer should have their sample collected, stored and kept, period.

Ms. {Castor.} Well, again, thank you very much for what you are doing. I will pass along to Dr. Dalton that you have kudos of the Moffitt.

Ms. {Barker.} He is a great catalyst.

Ms. {Castor.} Thank you.

Mr. {Pallone.} Thank you. Now, we have our last series of votes, a 15-minute and a 2-minute--I am sorry, a 15-minute and two 5-minutes.

Mr. Gingrey, you are next and you have 8 minutes. Do you want to try to use it?

Dr. {Gingrey.} Why don't I take a shot at it, Mr. Chairman?

Mr. {Pallone.} All right. You are recognized. The other members, if you want to go vote and then we will--

Dr. {Gingrey.} I think if you don't mind, Mr. Chairman, and I appreciate, I will go ahead. This is so interesting, I hate to lose my train of thought.

Dr. Barker, thank you so much for being with us and sharing this information. I have a medical background, but I can tell you, on this issue I don't know any more, maybe les

than my colleagues on the subcommittee. You talked a good bit about the state of the art in regard to the TCGA and being able to figure out subsets. You just mentioned, I think, in ovarian cancer and being able tailor specific drug therapy depending on the subset, which I think is fantastic, and this is a great thing and I am glad that are continuing to fund it, and I will certainly continue to support that.

I want to take it maybe a step further into the future and maybe you are already there, you haven't talked about it yet, but, you know, there was a study in the New England Journal of Medicine last year, I think it was called the REVEAL study. Are you familiar with that, Dr. Barker?

Ms. {Barker.} Yes.

Dr. {Gingrey.} Well, let me continue down that line then. In that study, it was on the impact of educating about genomic predispositions had on a patient's emotional state. Now, let me make it a little more personal and anecdotal. I had a first cousin deceased several years ago of Lou Gehrig's disease, amyotrophic lateral sclerosis, and he had a wife and three sons and a great life until he got this disease and it took him 3 or 4 years to die from Lou Gehrig's disease. Now, there will come a day, maybe it is already here and I want you to tell us about it, where every individual will go in for an annual routine screening physical examination, and

instead of just having several tubes of blood drawn and checking for blood type and different things and maybe an X-ray and an EKG, that they will have an opportunity to have their own genomes studied and maybe a printout that would suggest well, you are 20 years old, Mr. Jones, and your likelihood of developing Lou Gehrig's disease or Huntington's chorea or prostate cancer at some time in your life is a certain statistic or to a woman, same thing with breast cancer and ovarian cancer. But it is no assurance that that will happen to them, it is just a statistical likelihood or chance. How much of this information should be given to patients and what effect would it have on their lives in regard to something like, let us say, Lou Gehrig's disease which has no cure or Huntingdon's chorea, which has no cure? Should they know this? Is this something that people want to know or would it drive them nuts to have that information, say, 40 years before the occurrence of the disease?

Ms. {Barker.} So you raise an excellent point. I think we have reached a point in our society where advanced technologies are ahead of the extent to which we have actually incorporated this into our thinking and our planning. Genetic counseling is something that we are investing in but probably not enough, and I think we are going to have to do a lot more and I think genetic counseling

1447 will become very much a practice of medicine in the future.
1448 I am a bit of futurist so I believe that what is going to
1449 happen is that you will get your genome. I think you will
1450 know that your probabilities of getting certain diseases are,
1451 but as you point out, the chances are really going to be
1452 dependent on the environmental exposure you receive and
1453 dozens of other factors and so many people inherit
1454 predisposition for breast cancer, don't get breast cancer,
1455 and frankly, all the inherited genes that we know about in
1456 cancer today are responsible for only probably less than 5
1457 percent of all cancers.
1458 So I do think that people will want to know, and I think
1459 as we go forward, and I think the whole idea here is, we will
1460 develop prospective strategies for dealing with that both in
1461 terms of genetic counseling and ultimately interventions. So
1462 we haven't talked much about prevention today but I think as
1463 you understand the genomics of these diseases, you will be
1464 able to go in and figure out ways to prevent them. Now, it
1465 is going to take some time but I think it is going to
1466 catalyze a whole new field here of, you know, sort of
1467 genomics-based prevention, and that is what I am in favor of.
1468 But as you know, there are companies already today that are
1469 giving people their genomes, I mean, at least your germline
1470 DNA, the changes that you inherited, and they do have genetic

counselors. There are two or three of these companies now. And we are kind of watching that to see what impact that is having on patients.

Dr. {Gingrey.} Well, in the couple of minutes that I have left, let me ask your opinion on this. Do you think ultimately that this will reduce the cost of medicine or that it ultimately will drive it up drastically?

Ms. {Barker.} Well, I don't know the answer to the question but my guess is that there will be a blip as in all things and people will take a very high interest in this, and we just discussed, they will then realize that there are certain strategies that you have to undertake to mitigate you risk but that is pretty much what you can do until we can develop interventions to actually either prevent the disease or treat the disease effectively. So I think there may be some blip once everybody--you know, I think it is not going to be that long until everybody can get their genomes sequenced. So I think there will be a period when people have a high level of interest but I am guessing that will become integrated into our society and we will ease off. So I think in the long run it will reduce the cost of health care.

Dr. {Gingrey.} Well, I think in the long run it will too, and I think I agree with you on that.

The final point that I wanted to ask you about of course is the issue of discrimination, and of course as people get this information at a very young age and go out into the job market, how do we protect them from the possibility of being discriminated against because they have a high risk of developing breast cancer or colon cancer or whatever and as employers look at that or have access to that information? It would be so important to make sure that we protect that information.

Ms. {Barker.} And we do. I mean, I didn't mention that all of the data in The Cancer Genome Atlas is protected at a second level. If you want any access to patient data, you have to actually apply for it, and any good, you know, sort of validated investigator can access that data. We are also protecting the patients' data through informed consent, and of course, ultimately the Nation is protecting that data though GINA and many people have worked tirelessly to pass that bill a few years ago. So I think we have anticipated this. That doesn't mean that there might not be somebody who falls through the cracks here but we have done everything we can but we are going to have to stay ahead of this so that as more and more of this information becomes available, that opportunity doesn't become too much of a temptation for people to actually abuse their privileges in that regard.

Dr. {Gingrey.} Dr. Barker, thank you. My time is about up, and I thank you so much.

Mr. Chairman, I yield back.

Mr. {Pallone.} Thank you. Now, I don't think there is any time left on the Floor so I suggest everyone go over there. But Ms. Eshoo wanted to be recognized.

Ms. {Eshoo.} Thank you, Mr. Chairman. Unfortunately, I can't come back after votes because I have to attend an Intelligence Committee meeting, but I want to thank you, Dr. Barker. I am going to submit my questions to you.

I just want to make an observation, and that is that I think that there needs to be a healthy balance all the way around. You used that word in the beginning of your testimony. But also about advocates and advocacy. I remember a time where the NIH was reluctant for whatever reasons, maybe it was whatever was going on at the time with HIV/AIDS. It was the Congress that pushed it and the pushed the money into it in order to make things happen, especially to help care for the people that were afflicted, which we thought was going to be a pandemic at the time. So I have a lot of regard for the advocacy groups, and there is one that is going to be testifying today on behalf of pancreatic cancer. I think what I would like to know more about at some point is where the balance is between the atlas, the samples,

what we are doing with it, The Cancer Genome Atlas, but also the funding of the rest as we do that, because I think that there is a correlation between low investment in research and poor survival rates, and I don't think anyone can really get around that. We have never made a low and gotten a big bang for it.

So I think we need to explore these things and I hope, Mr. Chairman, we will invite Dr. Barker back because there is a great deal of hope riding on you and I think in your words we found a great deal of hope. Thank you, Mr. Chairman.

Ms. {Barker.} Thank you.

Mr. {Pallone.} Thank you. We stand in recess until these votes.

[Recess.]

Mr. {Pallone.} The subcommittee will reconvene. I think we have at least one more member who would like to ask Dr. Barker some questions. I yield to the gentleman from Texas, Dr. Burgess.

Dr. {Burgess.} Thank you, Mr. Chairman. I apologize for missing the earlier part of the hearing. As you know, we have several things happening simultaneously. That almost never happens up here on Capitol Hill, but today it did.

You know, one of the things that has come up from time to time--we had the FDA in last week or the week before.

There was a significant amount of funding coming to the National Institute of Health out of the stimulus bill last year. As I recall, that was a $10 billion amount that came to the NIH. What portion of that came to the National Cancer Institute?

Ms. {Barker.} About $1.28 billion.

Dr. {Burgess.} And can you give us an idea of where that funding is now? Has it all been allocated? Is there research now underway as a result of that? Where are we in the process with that?

Ms. {Barker.} Most of the funds have been allocated,, probably the lion's share of the funds have been allocated, and we will spend about $849 million obligated in 2009 and the remainder will be obligated in 2010. The funds went for special initiatives like The Cancer Genome Atlas, for example, where we invested in acquiring the samples and actually building the database and then Dr. Collins actually also invested money in sequencing these tumors. So some of the money went into the cancer Human Biobank. Much of the money went into, as you might imagine, individual investigator-initiated grants, and some of the money went into supplements to existing grants for investigators who had special projects. We funded quite a number of the innovation grants that actually came in, and overall, the lion's share

of the funds as they usually do go to individual investigators but we were able to fund several infrastructure, you know, kinds of programs like The Cancer Genome Atlas and also a lot of translational science, new clinical trials. This is probably the boost for cancer research that I have ever seen, I think the biggest and most catalytic action I have ever seen in cancer research. It has stimulated more thinking and more activities that I have seen in 35 years, and I think it is going to have a huge impact downstream.

Dr. {Burgess.} When you fund these research projects, was this money that was all allocated to be spent over 1 year's time or have you funded a research project that may gone on over multiple years?

Ms. {Barker.} Well, as you know, people are encouraged to spend their money in 2 years and to actually maximize the numbers of people that are hired newly and minimize the number of people who had to be let go in some of these institutions, but some of the grants will be extended over a couple of additional years, especially those that require longer-term objectives be met. So generally speaking, we are encouraging people to spend the money in the 2-year period allotted but there are certain kinds of studies that could proceed another couple of years if they have permission to do

so.

Dr. {Burgess.} What about the sustainability of research? It is an odd way to get money to get a big chunk of dollars like that. Obviously you have to make a commitment to scientists who are going to stay with you. What do you expect to see in the funding stream and the appropriations process over the next several years? How are we going to make that pitch to the appropriators? As I recall, we did the NIH reauthorization in 2006. It was a base of $30 billion with an increase of 5 percent, so roughly $1.5 billion a year over the 6 years of the authorization. We are coming to the end of that time. Has that been adequate in the way of funding, and now with this additional money that is coming in? Are we going to have other projects that need to be sustained? What do we look for in the future?

Ms. {Barker.} Well, I think the additional of $10 billion to NIH was an extraordinarily wise strategic move on the part of Congress and the President. I think it will be extraordinarily difficult, as you would expect, to reduce the numbers of investigators, to reduce the number of programs coming out of the ARRA period. So I think the decisions will be tough ones but I am hopeful that the pace of research and the pace at which things are moving right now in terms of

moving us towards a health care system that I think will be much more responsive in terms of reducing costs because we know what the disease is and how to treat it than continuing on the paths that we are on. I think it is one of the best investments we have ever made actually.

Dr. {Burgess.} And I don't disagree, but putting a bunch of money in, you are going to come up--you probably have some things that are in clinical trials. How do you see the interaction with the FDA going forward? You are going to have a lot of stuff that has to go through the FDA. And I can actually remember having this discussion with Andy von Eschenbach when he was at NCI before he was at FDA, and he was concerned about the FDA's ability to keep up with the pace of research, and this was back in 2004 and 2005 that he was doing when he was at NCI. So how do you see this playing out? Is the FDA going to be able to keep up with the pressure that you are going to putting on with the demand for approval of new drugs and new therapies and new techniques?

Ms. {Barker.} So Andy von Eschenbach, the same year you talked to him talked to me and said we need to put together an interagency oncology task force with FDA. We did that. And that task force has been working now for almost 7 years now, and I would say that--and we have been working on the science that is required to enable FDA to actually, you know,

review these drugs and devices accordingly. So many of our things fail because there hasn't been enough science done to actually inform the process. So what we have tried to do over the last 6 or 7 years is to sort of identify the regulatory science that has to be done, to work with them to determine what is a clinical trial going to have to look like, what do the biomarkers have to do to perform in a regulatory sense. We made a lot of progress in that regard, and so I think FDA--and there is a new announcement even a few weeks ago between the Secretary and Dr. Collins of a new relationship between FDA and NIH to do exactly what we have been doing, and that is, to really enhance this regulatory pathway by actually informing the science up front. So I think it is a relationship that has been built and will continue to be built, and I think FDA is anticipating this influx of new agents. For example, we work with them on nanotechnology products and so they are actually coming along and I think are on the same page with where we are.

Dr. {Burgess.} I am going to run out of time.

Mr. {Pallone.} You are out of time.

Dr. {Burgess.} How do you--

Mr. {Pallone.} You can't ask any more questions. Your time is over. Let us move on.

Ms. Schakowsky.

Ms. {Schakowsky.} Thank you, Mr. Chairman. I thank you, Dr. Barker, and actually all the witnesses who have been patient and waited with us.

This is really just thrilling, the genomics and the nanotechnology and the next generation. I am just wondering if we have all the personnel we need. I have had concerns that once an upcoming scientist leaves NIH for the private sector they don't often come back, and I wondered if this is a concern at NCI. What impact does it have on NCI's ability to advance promising research? Is this a problem where there is a brain drain at all?

Ms. {Barker.} So I think it is always going to be a problem because I don't think in our country we are placing enough emphasis in high schools and even earlier on science and mathematics, and that is a problem. We need to do more about that. I just came from China last November, and looking at the number of computational scientists they are training, for example, we are those computational scientists, and fortunately we can partner with these countries. But at NCI what we have attempted to do over the last 7 years is actually really look at the first-time investigator coming in for a grant. We pull out those applications. We call them star R1s. And we preferentially fund those young investigators. So I think we are doing fine in terms of

funding young investigators. I think where we are going to fall short is having individuals who know how to work in teams and actually areas like mathematics, as I said before, because the amount of data that we are creating, terabytes every week, has to be analyzed and we have very few individuals that we have trained to analyze this quantity of data. We don't have many Google experts in the biomedical research enterprise. So I think we are doing fine but I think we really need to be very proactive about this and our universities and our high schools and even in our grade schools have to start thinking about putting science and mathematics back on the agenda, the top of the agenda, so they can bring the best and brightest into this field. I can't imagine if I were entering college today, I mean, I cannot imagine what an exciting future they are looking at.

Ms. {Schakowsky.} Exactly.

Ms. {Barker.} It is absolutely stunning. You know, the choices are amazing but these kids all grew up with their computer games and game theory and those are the kids that will be able to analyze the data.

Ms. {Schakowsky.} Right, and they are used to changing technologies and being early adopters and being flexible. I think that we need to do a better sales job about just what is possible and soon in the fields of science. I was told by

the Northwestern University in my hometown that were it not for Chinese students that postgraduate programs in science and math would probably have to shut down, and now the foreign students that we certainly want to come in go home. They are taking the skills that they learn here and going back home.

Ms. {Barker.} In large numbers.

Ms. {Schakowsky.} Yes, and so I appreciate your emphasizing the STEM programs. I think we all have to get behind that. But I think if we could just paint a picture of the kinds of achievements that are possible for them as individuals, the kinds of teams that they could be working on that are going to deliver cures, it is just incredible. So I thank you for all your work, and Mr. Chairman, I yield back.

Ms. {Barker.} My pleasure.

Mr. {Pallone.} I think that completes our questions. Thank you for bearing with us and for your input. I know members talk about doing further hearings on this subject. We will certainly look at it. I don't know what exactly we can do but I do appreciate you being here today. You may get some additional written questions within the next 10 days or so from the clerk, and if you do, I would ask that you respond to them. Thanks a lot.

Ms. {Barker.} I really appreciate the opportunity.

Thanks to all.

Dr. {Burgess.} Mr. Chairman, may I just make an inquiry? Do we get at the committee level--it seems like in years past the NCI used to produce an annual report? Is that made available to the committee?

Ms. {Barker.} Yes.

Dr. {Burgess.} Mr. Chairman, could I just ask that we all get a copy of the most recent report? I think it would be--

Mr. {Pallone.} Is it something that is very voluminous?

Ms. {Barker.} No.

Mr. {Pallone.} You can get hard copies?

Ms. {Barker.} It is quite short.

Mr. {Pallone.} All right. Let us get some hard copies. Thank you.

Ms. {Barker.} All right. We will follow up with that. Thank you.

Mr. {Pallone.} I ask the second panel to come forward, if you would. Thank you for bearing with us. Let me introduce each of the members of this panel. Beginning on my left, she was introduced before, is Ms. Kristin Fitzgerald from Naperville, Illinois. Thanks for being with us today. And then we have Megan Gordon Don, who is the chair of the Deadly Cancer Coalition and director of government affairs

for the Pancreatic Cancer Action Network. And then from New Jersey is Dr. Robert DiPaola, who is a member of the American Association of Cancer Research and director of the Cancer Institute of New Jersey. And last is Jeff Allen, who is the executive director of the Friends of Cancer Research. We ask you each to give us a 5-minute statement, if you will. That becomes part of the hearing record and after that our own questions for 5 minutes each. As I mentioned, we may give you some written questions in the next 10 days or so.

So let us start with Ms. Fitzgerald. Thank you so much.

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^STATEMENTS OF KRISTIN FITZGERALD, NAPERVILLE, ILLINOIS; MEGAN GORDON DON, M.H.S., CHAIR, DEADLY CANCER COALITION, DIRECTOR OF GOVERNMENT AFFAIRS, PANCREATIC CANCER ACTION NETWORK; ROBERT S. DIPAOLA, M.D., MEMBER, AMERICAN ASSOCIATION OF CANCER RESEARCH, AND DIRECTOR, CANCER INSTITUTE OF NEW JERSEY; AND JEFF ALLEN, PH.D., EXECUTIVE DIRECTOR, FRIENDS OF CANCER RESEARCH

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^STATEMENT OF KRISTIN FITZGERALD

} Ms. {Fitzgerald.} Mr. Chairman, members of the subcommittee, I want to thank you for the opportunity to testify at today's hearing.

My name is Kristin Fitzgerald. As a former health staffer, I have participated in many Congressional hearings. This is, however, my first time on this side of the dais, and I greatly appreciate the opportunity to speak to the challenges facing cancer research. I am here today not only on my own behalf, but that of my husband, Ray Fitzgerald, who as you have heard was a staffer for Congressman Shimkus.

Ray died last January of gastric, or stomach, cancer. Until his diagnosis in May of 2008, Ray was a healthy 36-year-old man. He had no risk factors for cancer. He had

never smoked, drank infrequently, and lived a healthy lifestyle. With a large Irish family before him, there were only four unrelated incidences of cancer before him. Nothing would ever have put him at high risk of a cancer diagnosis.

Ray's cancer symptom was burping, which appeared for a period of 2 months before his cancer was diagnosed. When Ray was diagnosed, his cancer was an advanced stage IV. His gastric tumor had spread throughout the lining of his stomach and progressed to his esophagus and throughout his liver. We were told that there was no hope of a cure but that chemotherapy could reduce the cancer for a time. That time was 8 months.

This is not an abnormal scenario for gastric cancer. It is the second deadliest cancer worldwide. It very often presents in Stage IV, and is always incurable at that point. Ray however, was 40 years younger than the average gastric cancer patient, and thus the grim prognosis impacted not just Ray, but myself and our three young daughters, Nora, Maggie and Lucy. Nora and Maggie are here.

It is my belief that Ray's diagnosis and prognosis is our worst cancer nightmare: diagnosis of a deadly cancer with very few warning signs at an advanced stage where a cure is impossible. It is a death sentence. And if we think it can't or won't happen to us, we are wrong. Ray was one of

us, or at least in your case, your staff. And as I have learned, it could even be happening to one of us right now, and we would never know it.

After Ray died, I spent some time talking with Ray's doctors to see how this kind of scenario can be prevented so that more young dads and moms aren't violently stolen from their families by cancer. As a former health staffer, I assumed that gastric cancer research was ongoing and would utilize Ray's tumor specimen and facts about his age and health status to find a cure for this deadly cancer. However, far too little is being done to research gastric cancer and other gastrointestinal, or GI, cancers that have a similar deadly prognosis. CBS News analyzed the disparity in research dollars in May of 2009. For each cancer death, the most federal research dollars are spent on cancer of the cervix at $18,000 per fatality and breast at $14,000 per fatality, contrasted by the least funded, which is gastric cancer at $1,100 per cancer fatality.

GI cancers are some of the deadliest cancers in the United States with deaths attributed to the digestive system second only to those in the respiratory system. Four out of the five lowest 5-year cancer survival rates for metastatic cancer are GI, pancreas, liver, esophagus and stomach. And GI cancers are rising, particularly in young people. A

recent NCI article documented the rise in gastroesophageal cancers of the stomach and esophagus. This article compared the incidence rates in two 4-year periods, 1975 through 1979 and 2000 through 2004. Overall, there was a 44 percent increase in these cancers. Within gastroesophageal cancers there was an explosion of a particular type, adenocarcinoma, which is what Ray had. The increase in adenocarcinoma was 465 percent, with a 190 percent increase in young white males. And the situation for young people with GI cancers is particularly grim. Because GI cancers are considered to be diseases of middle or advanced age, the diagnosis in people under 40 is often delayed. As a result, the disease is usually in an advanced stage with a poor prognosis by the time the diagnosis is established. And their very age works against them. The strength and relative health of their bodies is passed on to their cancers, making them even more aggressive than in older patients. As a result, GI cancers in young people tend to be fatal.

Yet, unlike other deadly cancers, gastric cancer and many other GI cancers do not have a national clinical registry and tissue bank to utilize tumor tissue and clinical records for research purposes. In my view, this is intolerable. Congress and NCI can and should do more to ensure that researchers can have access to the tools they

need to prevent and diagnose these cancers before it is too late. Though these cancers are growing, they are poor candidates for wide-scale screening programs due to the smaller population of people impacted and the invasive nature of screening available.

More research is essential in order to understand the unique characteristics of the disease in younger people and develop a screening test based on molecular markers to allow for earlier detection. In order to accomplish this research, NCI must develop a coordinated national GI cancer tissue biorepository and accompanying research project to focus research in this area and make tumor tissue available for research purposes.

Last year the Labor, HHS, and Education Appropriations Report included language asking NCI to do just that. To date, this has not yet been accomplished. Congress must act to ensure that these cancers can be detected and cured so that more lives are not lost.

Ray was a wonderful man and his spirit will live on always. However, it is my belief that Congress should fund a research project, tissue bank and registry so that the physical legacy of a patient like Ray can live on forever, giving eternal gifts to researchers and scientists throughout the world.

Members of the subcommittee, thank you for your time and consideration. I am happy to answer any questions.

[The prepared statement of Ms. Fitzgerald follows:]

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Mr. {Pallone.} Thank you so much.

Ms. Don.

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^STATEMENT OF MEGAN GORDON DON

} Ms. {Don.} Mr. Chairman and members of the subcommittee, my name is Megan Gordon Don and I am here on behalf of the Pancreatic Cancer Action Network as well as the Deadly Cancer Coalition. I appreciate the opportunity to testify today regarding deadly cancers and the state of cancer research.

I am going to give you some background on the research problems associated with deadly cancers and why the Deadly Cancer Coalition was formed as well as provide you with four key recommendations for the committee's consideration. While a number of cancers have achieved 5-year survival rates of over 80 percent since passage of the National Cancer Act in 1971, and the average 5-year survival rate for all cancers has increased during that time from 50 percent to 66 percent, significant challenges still remain for other types of cancer. In fact, there are eight major cancers that have yet to reach the 1971 benchmark. Nearly half of the over 562,000 cancer deaths in 2009 were caused by these same eight forms of cancer, which are ovarian, brain, myeloma, stomach, esophageal, lung, liver and pancreatic. I have provided for

the record a fact sheet on these cancers, which we refer to as the deadly cancers.

As grim as the statistics are now for deadly cancers, the future looks even worse. According to an article in the June 2009 edition of the Journal of Clinical Oncology, cancer incidence is not only projected to dramatically increase in the next 20 years, but some of the deadliest cancers will be among those of the greatest relative increase in incidence.

In contrast to many of the other cancers with significantly better survival rates, research into the deadly cancers has been relatively underfunded, and as a result, these cancers have no early detection or treatment tools or the available treatments are still considered controversial. While there has been some work through the TCGA, as Dr. Barker highlighted, for three of the deadly cancers, and while NCI has expressed interest in expanding TCGA to more deadly cancers, biomarkers have yet to be identified or validated for the majority. Also, survival for these cancers is measured in weeks and months, not years.

Research into deadly cancers has also faced many hurdles including low priority status, little accountability, low average funding, little understanding of the research complexities by grant reviewers, deadly research grants are

rarely reviewed by experts in the field, and a shortage of available tissue.

Our coalition started with the premise that all cancer patients deserve at least a 50-50 chance of survival. And, at a minimum, survival from all types of cancers should be above the starting line that was established nearly 40 years ago. The fact that there are a set of cancers that have not reached that starting line, in most cases are not even close, indicates that the time has come to establish a targeted effort to focus on the greatest challenges with the greatest need: deadly cancers. These challenges are not insurmountable but it will take leadership, vision and a change in the current research paradigm at NCI. Specifically, we are calling for an increase in funding, the creation of a targeted deadly cancer program to provide structure and accountability, a dedicated grant program, and expert review of grants.

I want to note that our recommendations are not about telling NCI how to do the science. We are calling for an increase in funding because the data clearly shows that deadly cancers are currently not research priorities at NCI.

I would like to call the subcommittee's attention to two charts that I have provided for the record. The first shows NCI funding for the top five cancer killers. Lung and

pancreatic are two of the most deadly, and they also have the lowest funding levels. Looking at the survival rates, you also see that survival is the lowest. This chart demonstrates in very dramatic fashion that there is a clear correlation between low investment in research and poor survival rates, and vice versa. The second chart shows that less than 18 percent of NCI's funding has gone to the deadly cancers, and yet over half of the cancer deaths are caused by the eight deadly cancers. Across all types of cancer combined, the NCI spent just over $7,000 per cancer death in 2008. For the deadly cancers, NCI devoted only about $2,500. Taken together, these charts clearly demonstrate that the status quo is not working for the deadly cancers and some sort of targeted funding is needed.

Mr. Chairman, creating structure and accountability is absolutely essential to making progress. Therefore, a second recommendation is to create a targeted cancers program that includes strong accountability measures such as requiring the NCI director to develop a strategic plan to increase survival rates for the deadly cancers. Furthermore, we call for annual reports to Congress showing progress against the strategic plan to further ensure accountability.

Our third recommendation is to establish a new targeted grants program to create a protected pool of research funds

for the deadliest cancers. This additional grant opportunity will help to compensate for the limited existing data on deadly cancers which put these grant applications at a competitive disadvantage with the better researched cancers and allow these grants to be evaluated in a way that would foster more funding opportunities for both experienced and young investigators in order to attract more scientists to this field of study. Grant review committees would include scientific experts in the specific disease areas of interest, another critical point for deadly cancers in our fourth and last recommendation. We have presented the idea for a targeted cancers program to the NCI and have also been working with the House and Senate sponsors of the ALERT Act.

Chairman Pallone, on behalf of the Deadly Cancer Coalition, I would like to commend you and Representative Capps for your work on the ALERT Act. It captures many of the recommendations outlined above. Additionally for the pancreatic cancer community, passage of H.R. 745, the Pancreatic Cancer Research and Education Act, introduced by Representatives Anna Eshoo and Ginny Brown-Waite, is another important step to tackling the changes I have discussed.

Mr. Chairman, in conclusion, I want to thank you and members of the subcommittee again for allowing me the time to testify. The Deadly Cancer Coalition believes that the time

has come to create a new research paradigm at NCI that will lead to the institute tackling the hardest and most complex problems. It is by solving the hardest problems that we will likely see the greatest rewards for the entire field of cancer research. I am happy to answer any questions.

[The prepared statement of Ms. Don follows:]

********** INSERT 3 **********

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Mr. {Pallone.} Thank you.

Dr. DiPaola.

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^STATEMENT OF ROBERT S. DIPAOLA

} Dr. {DiPaola.} Good afternoon, Mr. Chairman and members of the subcommittee. My name is Dr. Robert DiPaola. I am director of the Cancer Institute in New Jersey, our State's only NCI-designated comprehensive cancer center. The mission of CINJ, similar to 65 other NCI-designated centers nationwide, is to reduce cancer incidence, morbidity and mortality through multidisciplinary cancer research including researchers in the laboratory collaborating with physician researchers in the clinic. I am also a member of the American Association of Cancer Research, AACR, which is dedicated to advancing cancer research, to prevent and cure cancer through research, education, communication and collaboration. Thank you for convening this 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. Through its oversight and legislative activities, this committee has played an important role in advancing cancer research, and I commend Chairman Pallone and all the members of the committee for their achievements and ongoing commitment to this national priority.

Today we estimate, as you have heard, one in two men and one in three women will develop cancer in their lifetimes. This year alone, almost 1.5 million Americans will be diagnosed with cancer and more than half a million Americans are expected to die of the disease. That is approximately 1,500 people a day, one per minute. The toll on the economy is staggering and predicted to increase with the increased risk of cancer to our aging Baby Boomer population if there is not dramatic intervention supporting the need to increase the investment in cancer research.

The Nation's prior investment in cancer research is reaping benefits to millions of Americans. According to the ACS, as you just heard, the 5-year survival rate for cancer has improved. The overall 5-year survival rate improved to approximately 66 percent compared to 50 percent in earlier years but we now need to go further, especially for rare and aggressive cancers. An example of a major advance that is providing for accelerated progress is the sequencing of the human genome and The Cancer Genome Atlas, as you just heard from Dr. Barker, which is now allowing us to answer difficult questions more rapidly. Research to improve diagnosis, treatment and prevention of cancer can improve patient outcome.

Currently, only approximately 5 to 10 percent of drugs

2087 that are first tested in cancer clinical trials are
2088 ultimately approved. We now have the models to improve this
2089 rate including a better understanding of molecular pathways
2090 that allow a more targeted and individualized approach. Much
2091 of the progress made in this country against cancer has been
2092 the result of organizations such as the AACR and of research
2093 in cancer care done at NCI-designated cancer centers. A
2094 culture of collaboration is also a hallmark of NCI-designated
2095 cancer centers in which collaboration between laboratory and
2096 clinical researchers and collaboration with other research
2097 institutions, industry and other cancer centers is
2098 encouraged.
2099 At CINJ, as an example, with NCI's support, we have been
2100 able to foster a consortium model with researchers at
2101 multiple institutions in the State including the best
2102 researchers at CINJ, Rutgers and Princeton universities.
2103 These efforts recently have led to the discovery of critical
2104 metabolic pathways involved in tumor cell starvation and
2105 survival and translated these laboratory findings into
2106 several clinical trials that are now ongoing and available
2107 for patients with both common and more rare cancers that are
2108 attempting to better starve tumor cells.
2109 Another area of funded research important to improve
2110 outcomes for patients is comparative effectiveness research

which seeks to optimize emerging and existing therapies. For example, a team of researchers in epidemiology recently published a landmark study that better defines the use of hormone therapy for men with early stages of prostate cancer. Other novel therapeutic trials with NCI support include a recently opened clinical trial to look at harnessing our immune system to tackle pancreatic cancer and other cancers, in this case administering in pancreatic cancer a new vaccine combination directly into the tumor, now offering many patients in need a new clinical trial option.

Other efforts to foster collaboration include the work of the AACR that underpins many efforts and groups such as Stand Up To Cancer. This new initiative provides large grants awarded to multidisciplinary research dream teams.

Cancer's economic burden is staggering. The NIH estimates that in 2008 the overall cost to society was more than $200 billion. Fortunately, we are at a most promising time in cancer research, as you have heard, but much more remains to be done. I think we have the potential to accelerate through this tipping point in time by supporting a new era of cancer treatment and prevention and gain on our investment to reduce the toll of cancer on the people and the economy of our Nation. Thank you.

[The prepared statement of Dr. DiPaola follows:]

2135 ********** INSERT 4 **********

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Mr. {Pallone.} Thank you, Dr. DiPaola.

Dr. Allen.

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^STATEMENT OF JEFF ALLEN

} Mr. {Allen.} Good afternoon, Chairman Pallone, Mr. Shimkus and members of the subcommittee. It is an honor to testify before you today. I am Dr. Jeff Allen, executive director of Friends of Cancer Research, a cancer research advocacy organization and think tank based in the Washington, D.C., area. I would like to thank the staff of this committee, who have worked tirelessly in putting together this hearing.

The foundation of Friends of Cancer Research, Dr. Ellen Sigal, could not be here today as she is with a loved one right now who is being treated for a rare cancer. Dr. Sigal started this organization 15 years ago after having lost a sister to breast cancer, her father to prostate cancer and mother to pancreatic cancer. This is as personal for her as it is for you, Mr. Chairman, and likely everyone in this room including myself, who have been deeply affected by this terrible disease. It is with this in mind that I am here today to express what we feel needs to be done to end the suffering that millions of cancer patients and their families experience every year. Exceptional progress has been made in the treatment of cancers, due in large part to the

investments in biomedical research. However, significant hurdles stand in the way of ending the burden of cancer.

Today it is estimated that it requires over $1 billion, 12 to 15 years and 1,000 patient volunteers to get a single drug to market. Chairman Pallone, 15 years to translate a new discovery to a therapeutic today by today's rates would mean a loss of almost 8.5 million Americans, approximately the population of your home State of New Jersey.

The funding allocation to biomedical research as a part of the American Recovery and Reinvestment Act presented a renewed opportunity for American investigators to carry out research projects that otherwise may not have been possible. However, in order to truly halt the devastating impact of cancer, a comprehensive approach is needed. First, increased collaboration across all sectors is needed to turn the next corner of scientific advancement. The NCI continues to be an engine-driving process but we must also acknowledge the need for collaboration with other agencies. For example, increased scientific capacity at the FDA is needed to ensure that the discoveries being made at the NCI get to patients as safely and efficiently as possible.

Second, the historic health reform bill passed this week takes many important steps to ensure that breakthroughs from research are available, accessible and affordable to all

Americans. This includes the expansion of comparative effectiveness research, which can help to provide improved information for patients and their health care providers. While it will take careful thinking to finalize many of the details moving forward, we look forward to working with members of this committee and others to ensure the success of these programs.

Finally, we must also tear down the silos that exist in biomedical research and focus on the common goal of reducing the cancer burden. Classifying and studying cancers based on their molecular characteristics as opposed to just their tumor site is in many cases the direction that science is leading. It is through the success of research that common molecular targets for abnormal growth have been identified in multiple cancers. While this adds to complexity, it also creates opportunities for shared success. This is not to diminish the important work of targeted focus but we must let our work support and inform those fighting for the common goal on our alternative fronts. The time of scientific opportunity is upon us. In order to ensure that multiple integral components of the health care system are prepared for the future of cancer research, we must act now.

We respectfully ask that members of this committee, the Congress and the Administration be steadfast in their

commitment to ending cancer. I cannot emphasis enough the need for collaboration. The advocacy community and entire research community must embrace our common goal and support science and collaboration that will enhance the battle against cancer on all fronts. It is our responsibility to represent patients' needs and what must be done to end the burden of all diseases. Thank you.

[The prepared statement of Mr. Allen follows:]

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Mr. {Pallone.} Thank you, Dr. Allen. I thank all of you, really. I want to particularly mention Ms. Fitzgerald. I remember when your husband passed away last year and how sad it was and a difficult time for Mr. Shimkus in particular, and I just wanted to thank you for sharing Ray's and your family's story with us today. Thank you.

I am going to recognize myself first. You know, I wanted to ask, I guess, Ms. Fitzgerald and Ms. Don, you know, you both described progress in our fight against cancer but that it has been limited progress with certain types of deadly cancers like pancreatic, stomach and esophageal cancer, and of course, I mentioned my mother, and one of the things that--I will try to be brief, but what happened was, I started doing research and I actually went on your Pancreatic Cancer Action Network site almost daily during that period of maybe 7 or 8 months from when she was diagnosed to when she passed away, and of course, the one thing that I kept finding out was that the problem was no early diagnosis. In other words, by the time you find out about pancreatic cancer, it is usually too late. In her case, though, there was a little bit of an early diagnosis because she had jaundice, and I basically found out from your website that that is one of the few cases where they do find it a little early if the person

gets jaundice and that is because the tumor presses on something, I guess the bile ducts or whatever, and the person turns yellow, which is what happened to her, and then she did have an opportunity. They call it the Whipple operation. And I have talked to a lot of people, even Members of Congress, who had the operation.

But what I wanted to ask you is, is that one of the reasons, and if not, what are the reasons why pancreatic cancer or a lot of these other deadly cancers are so challenging to researchers? Is the lack of an early diagnosis the main problem or what is it from a research perspective?

Ms. {Don.} It is actually twofold. One is the fact that we don't have early detection tools and the second is that pancreatic cancer in particular is a particularly difficult disease to diagnose. The pancreas is located deep in your body so it is not something that a doctor can feel on examination. As you mentioned, there really aren't that many early warning signs. It is usually lower back pain or jaundice, and typically with jaundice, the tumor is pushing on the bile duct and typically that is too late. So if your mother was a candidate for the Whipple surgery, then that was actually fantastic news because most patients are not. Only 15 percent of pancreatic cancer patients are currently

eligible for the Whipple procedure, which is a very, very difficult surgical procedure where they take out almost all of your digestive tract to get to your pancreas. So if only 15 percent of patients are eligible for the surgery, then that means that another problem is that it is very difficult to get tissue because you only get issue when you do surgery.

Mr. {Pallone.} Oh, you are saying because only 15 percent actually have the surgery, you just don't get much tissue to work with?

Ms. {Don.} Right.

Mr. {Pallone.} Of course, most of those don't last more than a year or two anyway, even when they have the Whipple, but I see your point.

Ms. {Don.} Pancreatic cancer also has a very high recurrence rate. Of the people who have surgery, 80 percent will have a recurrence within 5 years.

Mr. {Pallone.} Right. That is what they tell us. So now, is this lack of early warning the biggest problem not only with pancreatic but also with a lot of these other deadly cancers or that is just pancreatic?

Ms. {Don.} No, it is--

Mr. {Pallone.} And Ms. Fitzgerald can chime in too if she wants.

Ms. {Don.} It is a similar problem across many of the

cancers, and most of the deadly cancers we find at very late stages, so getting the cancers at earlier stages would be helpful but we also don't have treatments for them once we get them. As I mentioned, the best treatment for pancreatic cancer is a surgical procedure that even in the best case, 80 percent, still don't make it more than 5 years.

Mr. {Pallone.} Ms. Fitzgerald?

Ms. {Fitzgerald.} I think it is a combination. There are very few symptoms in many of the GI-tract cancers, gastric cancer. You know, like I mentioned, my husband's symptom was burping which is, you know, pretty often reflux or something of the kind--

Mr. {Shimkus.} Ray did that all the time.

Ms. {Fitzgerald.} But there are few symptoms, and I think it is also in the case of gastric cancer, a rapid progression. So you have very few symptoms, you have a rapid progression throughout the GI tract and then straight--because the stomach pumps out all your--you know, it gets your food and it pumps out your nutrients. It goes straight to your blood so it goes straight to your liver, so it is a rapid progression and right to basically all of your blood and so it goes throughout your body, and I think that is really similar on a number of the GI cancers, that they progress right to the liver.

Mr. {Pallone.} So is the problem then--in other words, is the reason why National Cancer Institute or others don't do a lot of research because they just figure that with all these problems and the difficulty of determining early diagnosis and cures, it is just not worth the investment? I don't want to put it that way but is that what is going on? They would rather spend money on other things where they think they can make more progress? Is that what we are getting?

Ms. {Don.} I think that from our perspective, and obviously I can't speak for NCI but from our perspective, it has been a case of we have gotten to a point where we encourage researchers to go after the lowest hanging fruit, and NCI funds the safe bets.

Mr. {Pallone.} Because this way they can show they are spending money, they want to show results.

Ms. {Don.} That, and there is a limited amount of money.

Mr. {Pallone.} But in a sense, I mean, at one level it makes sense because then they can show they have results. On the other level, they may be spending money on things that aren't as deadly and don't need--I mean, you see my point. In other words, why not spend money on the areas where we have such problems rather than the ones where we don't.

Ms. {Don.} And that is our central point, that we really believe the time has come where we have to challenge NCI to tackle the hardest problems, and the hardest problems are really the deadly cancers where we have made the least amount of progress. That doesn't mean there is not worthwhile research to be done on other cancers, on breast cancer and colon cancer and prostate and the others, but there is definitely a set of cancers that have not gotten the same amount of attention or really any sufficient attention, and it is time to focus efforts there.

Mr. {Pallone.} Thank you.

Mr. Shimkus.

Mr. {Shimkus.} Thank you. And I want to thank Dr. Barker for staying here and listening to the testimony. That doesn't always happen here in Congressional hearings, and I think it is to you credit. And I also now can see why the funding issue that we struggle with is very similar to the funding struggles that you have.

Ms. Don, kind of on the same line, but the question would be, NCI's efforts towards establishing The Cancer Genome Atlas, which was discussed at length, I think, how is that going to help research towards the deadly cancers, the pancreatic and gastrointestinal and others?

Ms. {Don.} Well, we certainly appreciate and want to

acknowledge Dr. Barker in particular for all of her work to try and ensure that deadly cancers are included. I mean, the three places where they started were three of the deadly cancers, and she has absolutely reached out to the deadly cancer community to try and get more deadly cancers included. I think the issue is that The Cancer Genome Atlas is one piece of a very large puzzle of things that we need to be doing for these cancers. It is a very important piece, as is nanotechnology, but we also need to be doing additional things to be able to understand the bigger picture and so we fully support TCGA moving forward, and from the Pancreatic Cancer Action Network's perspective, we absolutely hope pancreatic cancer is included and we can figure out a way to deal with the tissue issue with pancreatic cancer, but we need to focus on other efforts too.

Mr. {Shimkus.} Great. Thank you.

Kristin, again, welcome. We all miss Ray. And your daughters have been precious in the back. Let me ask you a question on the issue of federally coordinated national cooperation. Why is that so important in cases like stomach cancer that develop in young people?

Ms. {Fitzgerald.} First, I just want to publicly thank you and you staff for your tireless advocacy on behalf of Ray, and I know that he would be incredibly happy that we

were here at the Commerce Committee, his favorite committee, and this is a Congressional family. Ray's family was Congressional, many of whom are here, and I just want to thank you for helping and I know that it would mean a lot to him that we are helping to prevent this from happening to other people.

I think that I would say that NCI federally coordinating cooperation and collaboration on the case of GI cancers like gastric cancer and esophageal cancer is one of what I would think would be their truest missions, which in the case of someone like Ray where they are younger and they have a more rare cancer, that is a time where there really isn't a sample size that you need at any one institution. There are many institutions that are doing their best to really make a difference in curing people that have gastric cancer but they might see a handful of patients that are young like Ray, so in really attacking that question of what is happening in these cases with gastric and esophageal cancers that are happening in young people, collaboration is absolutely essential. Otherwise they just won't be able to make the kind of gains that they need. And they need--in the case of gastric cancer, they need a place to store tissue. They don't have a biorepository where they can store things. They need to be able to share that so they can make the research

2408 happening at any one institution benefit from the kinds of
2409 tissues that are coming into other institutions. They need a
2410 clinical registry which is coordinated on a federal level,
2411 all the kind of things that they can use to determine the
2412 kinds of influences that are contributing to these cancers.
2413 The coordination on a federal level helps to be able to solve
2414 that problem because of the smaller sample size at all the
2415 institutions that are working so hard.
2416 And probably most importantly, they need a coordinated
2417 federal research project because there are difficulties in
2418 obtaining gastric cancer tumors. When you are diagnosed with
2419 gastric cancer, you can't have surgery if you are stage IV
2420 like Ray because that would delay your chemotherapy and you
2421 would probably die. So you have to have mechanisms in order
2422 to develop a better tissue sample before it is treated with
2423 chemotherapy, and those are the kinds of things that NCI can
2424 perfect and disseminate throughout the United States because
2425 you are not having an endoscopy at a cancer center most
2426 likely. You don't think you are going to find cancer. And
2427 so even the community centers need to be able to get a sample
2428 size of the tissue that is untreated in order to have the
2429 kinds of things they need to make the truest gains in
2430 research. So it is probably in my view one of the areas
2431 where NCI can most be effective is coordinating all these

fantastic cancer centers that are doing their very best in these areas and really making those gains.

Mr. {Shimkus.} Thank you, and I have got limited time, but the 5-year survival rate for GI cancer is?

Ms. {Fitzgerald.} Well, for metastatic cancer, five of the worst survival rates, and I put them in my testimony, are GI. I think it is 1.7 for pancreatic. Liver is, I think, 2.2, 2.4 for esophageal, 3.4 for GI cancer. So, you know, folks with metastatic cancer, which is where it is often found for those GI cancers, they are not living.

Mr. {Shimkus.} Which is compared to some of the others where we have 95 percent early diagnosis, and I know they are different, but that is part of this debate.

My time is up but I just want to, if I can, Mr. Chairman, just go to Dr. DiPaola and Dr. Allen. Because we have had a big debate on this terminology and hopefully this terminology is maybe not the same, or I am trying to get-- comparative effectiveness research, which in the health care debate we talk about funding. Comparative effectiveness research, I hope, I gather from what you are doing, is finding the right response for the right disease, kind of like Dr. Barker talked about on the genome and the right medicine or whatever to affect that. What is your definition of comparative effectiveness research? Is it for directed

research or is it not for a funding process, is it?

Dr. {DiPaola.} It is a great question, and this comes up a lot. In terms of comparative effectiveness research, what we are really trying to do is do research to try to understand with many of the therapies that we have how to have better outcomes for patients, so how to take the therapies that we do have and appropriately use them to maximize their effect and outcomes for patients.

Mr. {Shimkus.} Not possibly minimize care based upon the cost?

Dr. {DiPaola.} I think that it should be focused on outcomes.

Mr. {Shimkus.} Dr. Allen?

Mr. {Allen.} Thank you. At Friends of Cancer Research, we spend a lot of time looking at this issue for really about the last 2 years, and in conjunction with the cancer community put together a policy white paper that I am happy to leave copies for the members of the committee if you are interested. But what this outlined was really from a broad perspective what can be obtained through comparative effectiveness research, largely focusing on the need for creating additional information, and I think we are in a fortunate position as far as the national infrastructure that is available in this country from the cancer research centers

funded by NCI to be able to collaborate better to create additional information that then can be a starting point for comparative effectiveness research but it is important as this funding is being allocated to fund comparative effectiveness research moving forward that we capitalize on the strengths of the different agencies to be able to really get to the answers to the questions that we are looking for and so comparative effectiveness and personalized medicine can actually go hand and hand and inform each other better.

Mr. {Shimkus.} Thank you, Mr. Chairman.

Mr. {Pallone.} Thank you.

Next is our vice chair, Ms. Capps.

Mrs. {Capps.} Thank you. Thank you, each of you, for your testimony. I had to miss some of the oral testimony but I am glad I could read the written statements that you made and I appreciate it very much. I have two questions, one to ask you, Dr. DiPaola, quite specific to the Cancer Institute of New Jersey. Then I have a more generic question to ask each of you.

So if I could ask you, Dr. DiPaola, your testimony described the work of the Cancer Institute and the work of the consortia. Can you just briefly highlight the issues involved in setting this up and the way this could be replicated in other areas of the country, how it could be

streamlined perhaps as a model?

Dr. {DiPaola.} Sure, absolutely, and I think that the consortia model is being done throughout the country, you know, and I gave an example in terms of what we are doing. CINJ as an NCI-designated center does have a consortia model, meaning there can be members, great researchers from additional institutions, especially locally institutions, that would basically allow us to share their science, work together and translate that science into clinical trials for patients. Right now we work together with many of the researchers at Rutgers and now even Princeton, and what I had described in my testimony was an example of that that has actually led to a better understanding on how to better starve tumor cells and has led to additional grant funding because of this team approach. Additionally, it has led to clinical trials that are operating right now that are taking that biology and that understanding from researchers from multiple institutions and putting it into designing new clinical trials.

Mrs. {Capps.} Thank you, and because of Dr. Barker's previous testimony, I can see the connection with NCI and then to you and then perhaps other consortia around the country too. I see a really good model.

Finally, I know that it has been mentioned already that

our recovery dollars have been a real boost to the NCI. The downside of that is that it is one-time or limited-time funding. I would like each of you to respond to this question. We all know that NIH has essentially been flat-funded during a good portion of the past decade. In your experiences, how has this affected cancer research, and particularly research on the deadly cancers, and briefly, how can we avoid that in the future? Just down the panel, if you will start, Ms. Fitzgerald.

Ms. {Fitzgerald.} I think that NIH and NCI are doing their very best.

Mrs. {Capps.} I know they are.

Ms. {Fitzgerald.} It is a difficult balance. I think one of the things that I would like to see is factoring in incidence but then factoring in mortality. You know, maybe there is a large portion of the United States that gets a particular cancer but if they have treatments, they are a little bit better off than, for example, my husband, who there just wasn't treatment available and so factoring in that, when you get this cancer, then you die, that to me should mean that there is a priority there in the federal research. So to the extent that new dollars come into the pot, that those are--and even with the existing dollars, they are apportioned in a way that includes looking at those kinds

of statistics.

Mrs. {Capps.} Thank you.

Ms. Don.

Ms. {Don.} So 2 percent of NCI's $5 billion budget goes to pancreatic cancer research. When you talk about ARRA funds, there are approximately 208 projects for all of the eight deadly cancers for a total of about 5.7 percent of NCI's ARRA budget. So we look at it, if these eight cancers are causing half of all cancer deaths, we are not trying to say that it should be X percentage or X number of dollars that should go to these cancers but it seems like there should be more than 18 percent of the overall budget, 2 percent in the case of pancreatic, less than 6 percent of ARRA funds going to the cancers where we have the worst survival rates, and as I stated earlier, I think that part of the problem is that given the flat funding, NCI has been looking for the safest bets instead of the most difficult research and the deadly cancers clearly are some of the most difficult and complex research.

Mrs. {Capps.} Let me shift the tone for you, Dr. DiPaola, given your testimony. Is there a way that the consortia could come partway to meet that diagnosis that has been given by the two previous, you know, how can the deadly cancers that need so much, is there a way that what you do

can help meet the needs that they propose?

Dr. {DiPaola.} Yes, I do think so. You know, as we especially work in teams, you know, teams of researchers that are really discovering new pathways and the biology and align them with the clinical researchers that are able to take it in the clinic or for clinical trials that are therapeutic or for new biomarkers that might be useful in diagnosis. I think as we support those teams coming together on a regular basis, we speed up that process so that that biology, which is cancer biology, can apply towards really any cancers, and especially rarer cancers. I can tell you that I spent this morning being part of a session at NCI, a symposium where we looked at a new biology focused on that area of metabolism actually called autophagy, and what was commented in the symposium was that that biology actually applies even best to the most aggressive cancers, so now what would be important, which we did there, was we had laboratory researchers presenting with clinical researchers is translate that to many different cancers but it is that same important biology.

Mrs. {Capps.} That is important.

Dr. Allen.

Mr. {Allen.} Thank you. Well, I think like any situation where there is a budget, there comes hard choices. But I think that with NCI leading the way, it must be

encouraged to look at what other components of the health care system can provide data so that cancer research is an ongoing and learning process. We need to look at the data that is available through other federal health-related agencies, and even as Ms. Fitzgerald mentioned earlier, with so many cancer patients being treated in a community setting, how cancer treatment can actually be research so that we learn more about the products we are even using now, because when they come to market, we don't really fully understand, particularly the impact that these products might have in different populations that weren't involved in the original clinical trials. So there is a degree of creativity in trying to capitalize and generate as much data as possible so that we are in a learning process continuously.

Mrs. {Capps.} Thank you, each of you.

Mr. {Pallone.} The gentleman from Texas, Mr. Burgess.

Dr. {Burgess.} Thank you, Mr. Chairman. You know, I think it is interesting on a historical note, this building that we are in, the Rayburn Building, Mr. Rayburn did die of pancreatic cancer and the diagnosis was just as Ms. Don described it. He came down with back pain, came back to Texas, was hospitalized probably back then under the care of an orthopedist for a while without much help to his problem, and ultimately succumbed to his disease. So I don't think

things were a whole lot different in 1961 than they are in 2010. It is useful to reflect.

Dr. Allen, I just wanted to ask you on the issue that has come up of course with The Cancer Genome Atlas and the issue of personalized medicine as far as treatment but what about prospectively? What about looking ahead at someone's risk? What if there were a way to screen people to understand where their risks were? Is that something that is on the horizon out there from a genetic standpoint, not just from the family history, not just from the things we typically associate but you have companies out there now sequencing human genomes for $987. Is that a useful part of what lies ahead for the next generation of researchers and doctors?

Mr. {Allen.} I think it is quite possible. The challenge is that right now at this point in time we may not fully understand what some of that information could lead to down the road or what it actually means at a point in time or quite frankly what to do in order to act and when a problem is identified. But I think this also goes back to the earlier question about how we try and gather long-term longitudinal data so that we understand the outcomes associated with some of those genetic tests that are detected. Ms. Castor described really a large project that

is going on at the Moffitt Cancer Center that is trying to do just that. As patients come in and are diagnosed with cancer, they are enrolled in a long-term database that allows for a great deal of follow-up. So not everyone can be enrolled in a clinical trial throughout their lifetime but if there is a way that we can try and capture more data about each individual person, share this across multiple centers and agencies, then we may be able to get to some of these longer-term answers much quicker.

Dr. {Burgess.} Where are you in that process? My father trained at Mayo Clinic back in the late 1940s. Part of his master's thesis was on esophageal cancer. Mayo Clinic has tissue from every patient they have ever seen since patient number one. Is there an effort to sort of consolidate and be collaborative of this mass of data that is out there?

Mr. {Allen.} I think there are some very good efforts underway. The challenge is the problem is so complex. One program that the NCI would be able to tell you more about is their cancer bioinformatics grid which looks to align clinical trial data from multiple centers across the country. This helps to essentially increase your patient base as well so hopefully like the others at the table mentioned, when you have smaller cancer populations enrolling for those trials is

an increased challenge so kind of connecting the data between others is underway. I think the challenge is that the data sources are do disparate right now that it is very difficult to align what you gain from a clinical trial versus perhaps administrative records like CMS that have more of a longitudinal look to things rather than a point in time kind of where clinical trial is a little shorter span.

Dr. {Burgess.} Well, with other areas in medicine, particularly with the push to electronic health records, we talk about particularly for hospital-acquired infections, for example, deidentifying and aggregating data so that trends can be spotted sooner than perhaps in the past. Is this type of work going on as far as surveillance of cancer? It seems like The Cancer Genome Atlas being developed, this would be something that people would want to do and in fact would be a priority.

Mr. {Allen.} Absolutely, and I think there is a great deal of interest in doing that. It is underway. It is expensive. But right now I think the biggest challenge, it is frequently done in isolated different centers so you mentioned the Mayo Clinic, which has a fantastic model and example and achieved many successes from it. But in order to really harness the power of this, it would be nice to try and adopt that and allow it to link in to other systems that are

doing very much the same thing so that we increase the pool, so to speak, the means to the end will be much faster.

Dr. {Burgess.} Dr. DiPaola, is that something that you are doing in New Jersey?

Dr. {DiPaola.} Absolutely. In fact, you know, one of the areas that we have increased dramatically over the last follow-up years was our bioinformatics area, and they are working with NCI in their efforts so that we do a better job in having clinical data associated with all of the issue and genetic data.

Dr. {Burgess.} What about the concept Ms. Fitzgerald raised? A lot of, particularly, well, in this case not early stage gastric cancer is diagnosed at an endoscopy center or an ambulatory surgery center, kind of different from the days when I trained, whoever was in the hospital, and it was not as big a challenge to collect tissue and get it down to the lab. Is there an effort being made to get collaboration from the endoscopy centers and ambulatory surgery centers for just this type of data collection?

Dr. {DiPaola.} There is. You just pointed out some of the things and challenges we need to overcome, and especially when things are in these trials including multidisciplinary approach, not only multidisciplines in terms of lab and clinical researchers but different disciplines in terms of

surgery and radiation oncology and medical oncology.

Dr. {Burgess.} But it does seem, Ms. Fitzgerald was telling her story and we have the other paper where it talks about the incidence of adenocarcinoma of the esophagus increasing. I mean, I have heard that story different names and different places but the same story, advanced-stage esophageal cancer being diagnosed at an ambulatory surgery center or endoscopy center if the incidence is indeed increasing, and this is not--I mean, this is the third time I have this story told. I did practice medicine but not GI. It just seems like that is something we should be perhaps a little bit more aggressive about, about getting the word out to our clinicians who are doing the endoscopies out in the field.

Ms. {Fitzgerald.} I don't think that the technology exists to get the kind of tumor sample that they want, right now, anyways. I mean, I think that it is important to get that little biopsy but what they really need is they need that whole tumor with those properties before it is treated and so they need, like, a little hole punch that goes all the way down and gets more of those tumor properties, and I think NCI is working on that but I am not sure that it is totally the kinds of tissue that we need for the kind of research that we need to do. I am not sure that that technology is

totally available.

Dr. {Burgess.} But, I mean, 15 years ago we were doing that for breast disease for estrogen receptors in the hospital. They weren't large tissue samples with ovarian malignancy.

Ms. {Fitzgerald.} And they haven't been disseminated, and I think the other part of it too is that in terms of clinical trials, many patients do not qualify for clinical trials because they are late-stage diagnosis. For example, my husband could not qualify for that so I think clinical trials are really important in terms of driving some of the funding but I think in the case of pancreatic cancer and some of these other cancers like gastric cancer, you simply are not going to be able to participate because you don't qualify and so there has to be a way of obtaining those kinds of tissue samples too.

Mr. {Pallone.} Okay. We are 3 minutes now.

Dr. {Burgess.} Sorry.

Mr. {Pallone.} That is all right.

The gentlewoman from Illinois, Ms. Schakowsky.

Ms. {Schakowsky.} Well, first of all, let me just express my condolences to you, Ms. Fitzgerald. As has been said, there is really not a family that hasn't been affected. My 38-year-old daughter-in-law died of cancer 5 years ago. I

admire your incredible composure. I am still not as good at talking about it as you were today. You are great.

Here is what I want to really understand from this testimony. One is the issue just of diagnosis. If there is not really major symptoms of some of these deadly diseases, then inevitably when they are diagnosed, they have moved along. So maybe this has all been said in the testimony but it is not just what we do about the cure. Yet your husband was burping. I mean, who doesn't, right? So what would drive--let us say he went for an annual checkup. What do we do about diagnosis?

Ms. {Fitzgerald.} You have to have a molecular screen on a cellular level. You have to have a blood test that could pick him up because there is no other way that you can prevent it because there is not a large enough population for these cancers that they will ever have the invasive screening procedures necessary that there would be for like colon or breast cancer. You just won't have an endoscopy screening program in the United States like you have a mammography or a colonoscopy program.

Ms. {Schakowsky.} Right.

Ms. {Fitzgerald.} You have to have that science. You have to understand that molecular change that somebody on their regular visit to their general practitioner has a blood

draw and catches that and either gets put into a screening program or, you know, catches the cancer and takes it out. You know, that is the only thing that would be able to get somebody in this kind of a situation.

Ms. {Don.} If I may comment, that is absolutely true. The other thing is that we do need more awareness for the symptoms that we know about. For example, in pancreatic cancer, we are beginning to see that there may be some evidence that otherwise healthy mean who all of a sudden have diabetes may actually have pancreatic cancer, and when they see their general practitioner their general practitioner isn't thinking about pancreatic cancer, they are thinking about treating their diabetes, and so we need to get more information out there about even back pain. We need to get more information out there so that more physicians are thinking about some of these other cancers from very seemingly benign symptoms and we absolutely need a good early detection test but we also need to get information out as it becomes available.

Ms. {Schakowsky.} Thank you.

Dr. DiPaola.

Dr. {DiPaola.} I absolutely agree with the other speakers. I guess what I would say is that, you know, with the research that is going on looking at the biology of the

cancer that leads to an understanding of what potential markers we could assess, which might be early diagnostic markers.

Ms. {Schakowsky.} Meaning when we take a blood sample or something?

Dr. {DiPaola.} I think that we need to continue to work toward discovery of even better markers as we learn the biology of cancer even more, and the problem is that once we understand that in the laboratory to really apply it in the clinic. We need to conduct very large clinical trials to validate that, and that becomes difficult, especially in rarer tumors, and I think having partnerships and collaborations to conduct those types of trials is going to be critically important. So even if we found and there are a number of potential markers to prove it and make sure that it is doing what it should be doing, we need these larger clinical trials

Ms. {Schakowsky.} So if cancer were present but it is not one of these common ones, is our goal to develop now some kind of a simple one-size-fits-all diagnostic tool that is a blood test of some sort or, I don't know, urine, whatever, I don't know, that would at least say there is some abnormality that is worth looking at?

Dr. {DiPaola.} Well, I mean, the goal would always be

to define the best and the simplest. I think--

Ms. {Schakowsky.} But are we looking for that? Are we anywhere close to that?

Dr. {DiPaola.} Absolutely. I mean, I think there are a lot of leads and it stems from understanding the biology better. I do think that kind of the partnership between the labs that are looking at the biology and these potential markers with the clinic need to continue to work together, but it will ultimately require validation in these larger clinical trials where many people need to be enrolled to really understand this.

Ms. {Schakowsky.} But is the thought, though, that some manifestation of the disease is more likely to show up? You seem to imply that even then in some of the rarer forms of cancer that it may not necessarily show up in some kind of a mass test.

Dr. {DiPaola.} No, I think that there is a lot of potential based on the biology and understanding new markers. There are new imaging modalities that are coming up all the time, so our ability to do things with greater technology have a lot of hope and I think our ability to collaborate so that we can conduct larger trials to prove or disprove and develop these different technologies is going to be important but I do think we need to look further, some relying on, as

you have heard, the current symptoms and current imaging modalities for many of these cancers is just not enough and so we are relying on new science and discoveries, new markers and developing them all the way through clinical trials to prove them and use them in the best possible way.

Ms. {Schakowsky.} Thank you. Thank you all.

Mr. {Pallone.} Thank you.

Mr. {Shimkus.} Before you could, could I--

Mr. {Pallone.} I yield to the gentleman.

Mr. {Shimkus.} Thank you, and I will be brief. Kind of following up on my colleague from Illinois's comments, I think part of that genome discussion I think earlier, one of my takeaways is that if we identify in essence an individual genome, and I would have thought that they would never change. Obviously there are changes that may occur, and then if people have that as part of their medical record, then you may get a better heads-up than before. Is that fair to say?

Dr. {DiPaola.} Absolutely. If you can start identifying populations that are at risk for certain cancers, then as you develop even, you know, the existing and the newer modalities whether they be imaging or new biomarker potential diagnostic tests, you would apply them more individualized and appropriate, especially for the higher populations.

Mr. {Shimkus.} And I guess the other takeaway is that we do--as we know, we always have the disease groups here. This funding issue causes people to struggle, and it is very compelling when you talk about mortality rates and where should dollars go. Now, we would hope that NCI would take that into consideration as they make these decisions versus intervention by us or other people. I was never one to want to direct funding because you want it to go to the scientists and you want them to apportion based upon due diligence, but there is a question about should mortality be given a higher priority, and that is kind of a takeaway and I don't know what we do from that.

And last, I got an e-mail. Kristin, folks who are watching, they are saying you are doing a great job and they appreciate your strength and fortitude.

Thank you, Mr. Chairman.

Mr. {Pallone.} Thank you.

Let me say before we conclude, it is very obvious to me and I am sure to everyone in the room that there is a great deal of interest on this panel in everything you have discussed, and I know it was mentioned that Ms. Capps and I are trying to put together some legislation and there is already, I think that you mentioned the pancreatic cancer bill that is already out there. I mean, there are different

things out there. So first of all, I will say we are probably going to have a lot of follow-up written questions to all of you just because we have so many questions. I know, for example, you both described the need for improved collaboration to ensure that scientific advances at NCI and others actually translate to safe and effective treatments, and I want to follow up with my staff about the three types of collaboration you discussed within the biomedical research community and with industry partners, so that is one thing I know we are going to get back to you on. But I am sure there are going to be others. So thank you so much. We really appreciate it. Usually we get back to you within 10 days or so with any written questions that we have, and I really appreciate your testimony.

And without objection, the Subcommittee hearing is adjourned.

[Whereupon, at 5:50 p.m., the Subcommittee was adjourned.]