

Yale CANCER
CENTER

answers

WNPR Connecticut Public Radio



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Yale Cancer Center Answers

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Welcome to Yale Cancer Center Answers with Drs. Ed Chu and Ken Miller. I am Bruce Barber. Dr. Chu is Deputy Director and Chief of Medical Oncology at Yale Cancer Center and Dr. Miller is an Oncologist who specializes in pain and palliative care. If you would like to join the discussion you can contact the doctors directly. The address is canceranswers@yale.edu and the phone number is 1-888-234-4YCC.

Chu This evening it is my great pleasure to be joined by our special guest Dr. Ellen Sigal, Founder and Chair Person of Friends of Cancer Research, a national nonprofit organization that raises awareness and provides public education on key issues relating to cancer research. They are also a strong advocate for new developments in prevention, detection, and the treatment of cancer. Ellen, thank you so much for being with us on Yale Cancer Center Answers.

Sigal Thank you, I am thrilled to be here and extremely proud to be part of this. Yale is doing cutting edge research and giving cutting edge care to patients. It's a great privilege and honor to be part of this.

Chu Why don't we go ahead and start off by discussing the main mission and goals of Friends of Cancer Research.

Sigal First of all, Friends is a coalition of all the major groups in cancer research; we have the American Cancer Society, ASCO, the Cancer Center's patient groups, and the Hollywood community and others. Our goal is very clear – public education on the importance of cancer research. Cancer research is what is going to find cures, make a difference, and give us knowledge to help those that will get the disease and those who are being treated today for the disease.

Chu This is a unique organization. I am not aware of any other group that encompasses all the major cancer societies and public efficacy groups as yours does. I understand that you also have this public-private partnership collaborative arrangement as well as part of your organization.

Sigal Correct, you will find maybe a thousand groups that care about cancer research and have that as part of their mission; however, what we do is unique. First of all, we care about all cancer research, we are not disease specific. We encompass a basic science, basic research is going to get us answers and knowledge, but we also deal with all diseases and all types of research. We are not organ specific and we care very much about the application of that cancer research. Basically how we accomplish that mission of public education is through collaboration; working with all cancer centers, all stakeholders, public-private partnerships, we publish on it. We work with congress and the White House to make sure that all

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citizens are informed of opportunities and challenges. As an example, recently we published a white paper from the academic community and all vested stakeholders on the importance of drug safety. It was also quite important to talk about the pipeline and the risk and benefit because there is risk to disease. When you have a disease, you want to make sure you are treated for a cure, or certainly to delay the onset of that disease, so you have to look at risks and benefits. We try to take context to public issues that are very challenging and weigh in from the research or academic community's perspective on these issues. We handle this through partnerships.

Chu Picking up on this white paper that you mentioned that focused on drug safety and efficacy, obviously that's a critically important issue as it relates to cancer patients. It highlights the critical need for our being able to identify new, more effective agents, that are at the same time safe and don't carry increased risks to our patients.

Sigal You also have to look at the stage of disease and the criteria because cancer is not a particularly safe disease. If you have early stage cancer you certainly want to take a look at the safety and the profile of any agent you are taking. You want to look at the toxicity and quality of life. There are patients struggling with metastatic disease that have a very grim outlook. At that point, one would be willing to take a bit more risk, but it is very individualized and we feel that knowledge is extremely important. Patients need to understand the risks they are taking. Sometimes they are unexpected risks, but you have to balance that with the disease and the dangers of that disease. It is not simple. We all want safe drugs. We all need knowledge, but if you are dealing with a disease that is likely to take your life, you may take more risks. At the end of the day the decision is between the patient and their physician with as much knowledge as humanly possible.

Chu Your group should be applauded for providing the tools that help to empower the patient and the interaction between the patient and physician to make these informed decisions.

Sigal Correct, they have to be informed, but we also have to understand that we can't have knowledge of it all. We have to make sure we get the knowledge in a timely manner and understand the knowledge.

Chu As I understand, you also have a very unique collaboration with the folks at the FDA to try to enhance this entire drug-approval process.

Sigal It is still a firm belief that all stakeholders have to work together and all

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government agencies have to connect with one another and the public. We have facilitated a public-private partnership. A few years ago we started a partnership with the AACI and all cancer centers on the importance of clinical trials and clinical trial approval. We work with the foundation for the NIH for eye service, head of the public-private partnership. We discovered that who was missing from the table was the FDA. We gained some insight on how critical they are, and right now, we are working with the FDA in a public-private partnership on biomarker validation. It is a partnership between the research community that goes beyond cancer, although we have two major cancer projects. It is the pharmaceutical industry, it is patient groups, it is the research community and the NIH, the payers, CMS, and the FDA that look at validated biomarkers and two particular projects in cancer, a validation of FDG-PET for lung cancer and for lymphoma. It is a very unique partnership and now with the legislation just enacted on the reauthorization of the FDA, there is the Regan uall and that will allow partnerships on very important questions including safety.

Chu It is interesting, in the press and the media sometimes the FDA gets a bad rap for being excessively rigid in their review processes of new drugs, but I think the public doesn't have a good understanding of the very limited resources that are at the FDA's disposal to take a comprehensive look at all of the various issues related to new drugs and existing drugs.

Sigal It is only recently that we have a confirmed commissioner of the FDA. We have had years and years of no, or acting, directors of the FDA. It is very difficult when you have that kind of situation to have leadership. We do have a confirmed leadership and an extremely capable leadership; however, the agency has been starved of resources for a very long time. Their mission is public health, food, and safety, 25% of the GDP. That is a huge mission and the complexity of what they have to do is extremely hard. There was a scathing report commissioned by the commissioner of the FDA looking at the science integration in to a regulatory environment. Although the mission had nothing to do with resources, the people that were on this committee to look at the integration of science, said that they were starved of resources; therefore, they are starved of systems to help them in their mission. You can't hold an agency accountable without giving them the resources they need. On the other hand, the issue of safety is extremely important. We need to have safe drugs but what you take for a headache is going to be very different that what you take for a chronic disease. There is a spectrum of disease from diseases that are easily treatable to very late stage diseases that are very complex, but this integration of science into that agency is critical and it cannot be done without personnel, resources and partnerships.

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Chu Obviously your group has played a key role in trying to provide education and raise awareness on behalf of our congressional delegation, because there is a sense that they don't have the same insights and appreciation of what the needs are for the FDA and other regulatory agencies.

Sigal There is a basic kind of inertia that we are facing, not only at the FDA, but certainly with the NIH, MCI and other agencies. There has been a doubling of the budget and an enormous amount of resources that have come into the NIH particularly. Some people think, "Well we doubled your budget but haven't cured cancer," so there is a lot of complexity in the public in terms of how cancer research gets funded. People don't really understand the mechanisms that a large percentage of the research that is funded comes from the Federal Government, but it doesn't stay in Washington. It goes to wonderful cancer centers like Yale and other centers. We have been diminishing over the past few years and that means young people cannot be funded, that means application and knowledge is delayed. It requires a lot of science and a lot of resources, so it is a matter of reassessing our national priorities, but also understanding what's been going on. It is a very complex message and I do not think a lot of people understand what's been happening to biomedical research in our country, specifically cancer research.

Chu Let's just take a step back. When did you start Friends of Cancer Research and what was the reasoning behind embarking on this very remarkable group?

Sigal We had our 11th anniversary recently. All stories are personal, but my sister died of breast cancer 22 years ago and left a 4-year-old child behind. It was very devastating because she was extremely young and I started getting involved at Duke and I realized that if one really wants to deal with cancer research or really wants to do something about it, one has to do it at the Federal level. I was lucky enough to be appointed to the National Cancer Advisory Board and the director was Richard Klausner who is a Yale graduate.

Chu Yeah, a good friend.

Sigal A good friend of cancer research and an extraordinary director of the National Cancer Institute. 10 or 11 years ago it was the 25th anniversary of the National Cancer Act and he wanted me, as a member of the National Cancer Advisory Board, to do something. We realized that it was very difficult to do something within the constraints of the advisory board, so we decided collaboratively that the most important message is the continued effort in research to get the answers. We decided to bring the

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community together around the 25th anniversary and celebrate the importance of cancer research, but also inform and educate people on the complexities and how people need to deal with this issue together. That is how Friends was formed. It was initially formed for one year, but now 11 years later, I am still doing this.

Chu As all good things, they continue. We would like to remind you to email your questions at canceranswers@yale.edu or call 1888-234-4YCC. At this time, we are going to take a short break for a medical minute. Please stay tuned to learn more information about Friends of Cancer Research with my special guest Dr. Ellen Sigal.

Medical Minute

It is estimated that over 2 million men in the US are currently living with prostate cancer; one in six American men will develop prostate cancer in the course of his lifetime. Major advances in the detection and treatment of prostate cancer have dramatically decreased the number of men who died from this disease though. Screening for prostate cancer can be performed quickly and easily in a physician's office using two simple tests, a physical exam and a blood test. Clinical trials are currently underway at federally designated comprehensive cancer centers like the one at Yale to test the innovative new treatments for prostate cancer. The patients enrolled in these trials are given access to experimental medicines not yet approved by the Food and Drug Administration. This has been a medical minute and you will find more information at yalecancercenter.org. You are listening to the WNPR Health Form from Connecticut Public Radio.

Chu Welcome back to Yale Cancer Center Answers. This is Dr. Ed Chu and I am here with Dr. Ellen Sigal, director and chairperson for the Friends of Cancer Research, talking about efficacy for cancer research and funding. Before the break Ellen, we were talking about how you started off with Friends of Cancer Research. You are now celebrating your 11th anniversary. What do you see as some of the major accomplishments of your organization?

Sigal It is complex. When we started 11 years ago our mission was the education of public-private partnerships at town halls. Initially we started with the public education and our cornerstone that makes us unique is what we call our town halls. We have them all over the country and we recently had a very successful town hall at Yale. What we try to do is bring people together from the community. We think the public really needs to be educated on the science, what's happening in their community and the research barriers and opportunities. Our format for the Town Halls is pretty simple. We bring together a member of congress who is very involved, members of the academic centers who are doing the

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research, someone representing government, and the patients, real people, to understand accomplishments, the complexity, barriers, and where we are going. We did a Town Hall at the University of Michigan with congressman Dingle, which was extremely successful. We had an overflow. We did one at Ohio State with the same situation, a senator and a member of congress. All communities have to be together. We are not going to solve this problem without that. We do 3 to 4, sometimes 5 to 6, a year. We are very strategic about where we do them, and we also think the public-private partnerships are extremely important, so we did one on clinical trial accrual. We are doing one on biomarkers with the foundation for the NIH. We worked with the Hollywood community. The Entertainment Industry Foundation recently funded a project on breast cancer biomarkers, which is a technology project that deals which centers all over the country looking for an early biomarker or blood test for breast cancer. That is the collaboration that we worked on and facilitated with them. We are now looking at other partnerships that we think are extremely important. We also are very concerned about regulatory policies and look at complexities of science and barriers. We worked to republish the white paper on drug safety. We are now looking at comparative effectiveness. People want to make sure that the drugs they get are effective and price sensitive. On the other hand, we care about the pipeline so they are very specific issues that we work on together. This year's issue clearly is going to be the integration of science into the regulatory policy, which is very important, the impact on the drug safety legislation to make sure we get better knowledge on the safety of drugs for patients and bringing communities together on those issues.

Chu You also host and organize an educational day on Capitol Hill.

Sigal Yes.

Chu That must be the forum and opportunity for folks involved in cancer research to relay key messages to our senators and congressmen.

Sigal We have multiple audiences for our messages. We do a lot with newspapers and ad. However, the cornerstone of Friends is the importance of cancer research. Cancer research is performed all throughout the country at our academic centers. The science that is going on, the basic research at very basic levels happens at these centers. It is extremely important for members of congress to understand that the commitment that they have to NIH, and specifically the NCI, happens at centers. 85% to 90% of a \$5 billion budget is distributed to the centers. The economic help, or that commitment happens in the communities that they fund. For an example, when we want to talk about capital help, we want them to

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know that the Yale Cancer Center receives money and that research makes the difference in what is happening at Yale and the centers all thorough the country. We work with the AACI, which is the collaboration of all the cancer centers, the academic centers, and the AACR, and we go with these scientists and with patients to talk to the members of congress on the importance of sustained commitment to cancer research.

Chu That is critically important. We a recently had a Town Hall meeting here at the Yale Cancer Center where your group Friends of Cancer Research were the main sponsors. It was very well received by the Yale community and by the patients who attended that Town Hall meeting.

Sigal Thank you. We think it is important and would like to be able to do more locally. They say all politics are local, but disease and treatment is local too, and the community of New Haven is very fortunate to have such a prestigious center. There are centers all over the country, but it does make a difference where you get treated. It makes a difference in the research that is happening and the education and in the dissemination of that knowledge. We are research oriented and care deeply about what these centers are doing and help the centers.

Chu Your group, and you in particular, really should be applauded and commended for the terrific work you do in sending that message out to the public. Ellen just tell us what you see as some of the major obstacles, in allowing that flow of research from the basic laboratories to the clinic, and then back from the clinic into laboratory.

Sigal There are huge hurdles today. Starting with number 1, resources and funding. Flat funding of research at the NIH and FDA really hurt the application of knowledge to all citizens. If we do not fund and make health care and health care research a priority, we are not going to be able to get better, less toxic treatments, or the knowledge to prevent disease. The number 1 hurdle is resources. The NIH has to be funded and it has to be funded at a sustainable level because we have to get knowledge from young people in research. Other issues that really worry us a lot are that we tend to demonize agencies, not that there aren't problems in the agencies, but they don't have the resources. As an example, the issue of safety is extremely important and everyone needs to have knowledge on the drugs they are taking. On the other hand, you have to look at risks and benefits. When taking aspirin, we need to know there are some risks to it, but benefits as well; the same thing with chemotherapy and diagnostics. Knowledge is extremely important but we have to stop giving mixed signals too because when people are taking these drugs they normally have very dangerous disease. You have to look at the spectrum

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of disease, but the most important thing is innovation. We have staggering science today. With molecular targeted drugs and prevention, as we start to understand biomarkers and what causes this disease, we will be able to intervene at earlier stages. We have to understand our goals and often we do not articulate about understanding what is at stake.

Chu You have had a very unique role as founder of Friends of Cancer Research and you serve on the National Cancer Institute Board of Scientific Advisors. You also serve in the NIH Foundation Board. What progress have you seen over the past 10-11 years in the field of cancer research?

Sigal First of all I want to state that I just recently was appointed to the Regan-Udall foundation, which is the foundation that is set up at the FDA through congress, so I am very glad because that mission is really to support the mission of the FDA, and the integration of science and safety. It is extremely important to acknowledge that we have made a huge difference. I am frustrated because this is a disease we can detect earlier, and treat more effectively, we have enormous knowledge. What we give the patients is more intelligent today, and you know, we can treat people that will live a long time with this disease. We've cured more people and there is an enormous amount of progress, so we have to be very proud. We used to view cancer as one disease.

Chu It is really quite remarkable how far we have come in the whole process. In the last 30 to 40 seconds that we have Ellen, and it is amazing how time has flown, what are some of the new initiatives that your group is focusing on as we are looking to 2008?

Sigal Always the importance of research funding and integration of science in the FDA is extremely important to us because if it works it is going to make a difference. We have to be able to have diagnostics and treatments for cancer patients. We will continue with the Town Hall series and we will continue to fight for research. We live for research and the only thing that will benefit patients is knowledge. Those are really important issues for us and want to make sure that we are well funded and have better diagnostics and better treatments for patients.

Chu Ellen it has been a real pleasure to have you with us on this evenings show, and on behalf of the Yale Cancer Center, I just want to thank you for all of your tremendous efforts on behalf of the cancer community and your goal for advancing all aspects of cancer research.

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Sigal Thank you very much, we are proud to be part of this and we were very proud to do the Town Hall. Yale is a spectacular place.

Chu We look forward to having a future Town Hall here at the Yale Cancer Center.

Sigal Definitely.

Chu Until next week, this is Dr. Ed Chu from the Yale Cancer Center wishing you a safe and healthy week.

If you have questions, comments or would like to subscribe to our Podcast, go to www.yalecancercenter.org where you'll also find transcripts of past broadcasts in written form. Next week we will learn about the latest advances in stem cell transplantation.