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Transcript

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Prostate Cancer: Fighting the FDA for your Life
Health Radio
Mike Kearney
Ted Girgus
Eduardo Garcia

Andrew Schorr:
This is Andrew Schorr, and we are live on Patient Power, and we've had some technical problems, but we have a very important show to talk about, and that is if you are facing a life-threatening condition, should the FDA stand in the way of you having access to drugs that are very promising but where they're requesting more data to consider approval? In other words, maybe there is data that shows it's very convincing, but there is some obstacle at the FDA even though many doctors and scientists say it has great validity. Should people who are worried about a terminal condition, should they have access to these drugs in the meantime?

Well, there is a lawsuit about just that, and so that's what we're going to talk about today. I'm just going to share a little bit of my own personal experience, and that is about a year ago, I was asked to testify at an FDA Oncology Drug Advisory Committee hearing. So, I went to Maryland, and it was related to a drug for the condition I have, and that is chronic lymphocytic leukemia. And the idea was it was a drug that might be helpful for people where other drugs have failed, and that drug is called Genasense, and years it has been in research for another condition, multiple myeloma, and then in CLL. Well, there were couple of problems I noticed just attending the hearing. One was that the leading experts in CLL for the most part were not part of the advisory panel that the FDA had put together. That was the first thing. The second thing was is that the doctors who were on the panel, many of them were experts in other kinds of cancers, particularly solid tumor cancers. So, what happened was, was that I felt the vote, which was largely against approval of the drug, was kind of a stacked deck with no knowledgeable people about the disease on the panel, and the FDA I think also was very vigorous in not giving it a fair hearing, and that they almost made a summation to the jury at the very beginning before the data was presented. So, it kind of bugged me. Well, it

turns out that this is not just related to this drug, which unfortunately now it looks like it won't go forward, it is not clear yet, but there are other drugs that are even more promising. There is one in prostate cancer; a cancer vaccine called Provenge, and so even though there was a vote in this case by the advisory committee by the doctors who fortunately were familiar with it that it was safe and that it was effective, the FDA wants more data.

Well, what does that mean for men with advanced prostate cancer where the hope is that this drug could work for them where maybe others are failing, and that's really what our program is about today. We're going to meet somebody who has started an organization called Care to Live. Mike, how do you pronounce your last name? Is it Kearney? Is that right?

Mike Kearney:
It's "Carney."

Andrew Schorr:
"Carney." And where are you Mike?

Mike Kearney:
I'm in New Jersey.

Andrew Schorr:
Okay. So tell me, did I sum this up right? You've formed your organization. You've had cancer touch your family more than once, and you kind of feel there is an injustice going on with the FDA where they're keeping Americans at their sickest time, some of us, from drugs that could lengthen or save our lives?

Mike Kearney:
That is correct, Andrew. Care to Live is a not-for-profit corporation. It came into existence as a patient advocate group. We helped support the Provenge Now rally in Chicago and the rally in Washington D.C., and then we helped place an ad in the Washington Post pertaining to this advisory committee vote that you said. It was voted safe, and it was voted effective. The vote was 17-0 safe and 13-4 that they said it had substantial evidence that it works. Well, now Care to Live has turned to litigation as the only remaining alternative. Care to Live hopes to get safe and effective immunotherapy to patients who have no other options, and we want to get it to them now. This is an emergency.

Andrew Schorr:
Well, it is certainly an emergency if somebody has more advanced prostate cancer and there are experts who say, you know this cancer vaccine could help you in your

case, but too bad, the FDA has delayed it, and the delay could be, what, many month? A year? Several years?

Mike Kearney:
We've heard anywhere from halfway through next year to the end of next year. It could go all the way out to 2010.

Andrew Schorr:
Right.

Mike Kearney:
These gentleman, they just don't have that time. Someone dies every day of prostate cancer, so we're seeking an emergency temporary and permanent injunctive order from the court as well as declaratory judgment that the FDA did arbitrarily and capriciously deny dying and terminally ill patients access to a safe immunotherapy.

Andrew Schorr:
Now, you've been talking with some other organizations too, and I bet you have gotten the sense that this has happened other times too.

Mike Kearney:
It seems like it's happened a lot recently. I think Mike Huckman of CNBC just had a program on where he talked about 55% of the drugs are being delayed like this compared to last year at this time. So, 55% of them the FDA is keeping, and there are some good immunotherapies. There is one for the bone cancer for the children, and we have some doctors who are just astounded that this stuff is not being given to the people who are in such dire need.

Andrew Schorr:
Right, and I think the other point that I would make, I mean, I know there are concerns. Surrounding all this you have generally senators and congressman get all upset. Is the FDA approving drugs too easily? Whether they're pain medications or for a variety of conditions, and certainly we had some notable ones that were pulled off the market even after they had been on the market for several years. And so, when you take that now to, for instance, the cancer area though, we're talking about life-threatening conditions and where people can't wait, and also I think wouldn't you agree that in the case of prostate cancer, these men with really a late-stage illness would take the risk. They would want to be informed of the risks, and if there are concerns if the FDA says well, we wish we had more data, but still the patients would say, but still make that drug available for me.

Mike Kearney:
Yes, I feel like the FDA can paint it how it wants. It granted Dendreon's Provenge fast-track status. It saw enough evidence there that there is something to really look at. So then it called an advisory panel, and Dendreon presented its Provenge, and then the FDA had three folks present what Dendreon had presented to them, and they asked that the advisory council advise them. Well, the 17 people that the FDA picked said 17-0 this drug was safe, and then 13 of them said, it shows substantial evidence that it works. So, we don't understand what the problem is.

Andrew Schorr:
Right. Right. So, I know there's a rally coming up, and you've been involved some, but I saw a rally involving a whole bunch of drugs and different organizations coming up in mid-September at the FDA to try to draw attention to this.

Mike Kearney:
That is correct. That rally is going to be on September 18th outside the FDA, and it's, like you said, it is for several drugs, for Provenge for prostate cancer, Genasense for myeloma.

Andrew Schorr:
We're back live on Patient Power, and hopefully you can hear me pretty well. We're doing the program a little differently today, but we have some very important content, and really the idea is should the FDA and its approval process stand in the way of drugs that where scientists are very positive about? But maybe there are still some questions about some, you know, dotting the I's and crossing the T's on some data, but the people with really terminal illness who the scientists and their doctors agree could possibly benefit from those drugs, shouldn't they be available to them?

Let's talk to somebody who is in clinical trial for the prostate cancer vaccine that we're discussing as an example, Provenge. Eduardo Garcia, who is in San Diego. Right, Eduardo?

Eduardo Garcia:
Yes, that's correct. I'm in San Diego.

Andrew Schorr:
And you're 84 years old. And I imagine you have more advanced prostate cancer, and you were in a clinical trial for this drug, Provenge, correct?

Eduardo Garcia:
Yes, I was very lucky to have that chance to do that.

Andrew Schorr:
Well, that's what I was going to ask. Did it help you as far as controlling the prostate cancer?

Eduardo Garcia:
It not only helped me control the prostate cancer, it helped me live six years.

Andrew Schorr:
Wow.

Eduardo Garcia:
And I'm talking about living normally, you know, with the quality of life, as you call it. Before I had the treatment, I was feeling terrible. You know, I was tired. I didn't want to go out of the house or anything. Now I have a normal life. I travel. In fact, I was in Washington not too long ago talking to the panel that they had with the doctors from the FDA.

Andrew Schorr:
Right.

Eduardo Garcia:
And so, you know, I have a normal life. Thank god for that.

Andrew Schorr:
So, Eduardo, when the FDA makes the decision to ask for more data and delay approval, even though the hearings were very positive for the manufacturer, Dendreon, which coincidently is here in Seattle where I am, you must have just been baffled.

Eduardo Garcia:
Definitely. It was because I thought that when those doctors, you know, they okayed that part, and so they probably know more about it than the FDA, so I don't understand why are they hesitating to okay it since it's completely harmless? Nobody has been sick taking that treatment. Maybe it's not a miracle drug. It has not saved everybody, but it certainly saved some people, and if they are going to give you even 2 or 3 years out of your life, it's worth it.

Andrew Schorr:
Right. I couldn't agree with you more. Let's meet another gentleman who has been affected by prostate cancer, and I hope I pronounce this right, Ted Girgus. Did I get it right, Ted?

Ted Girgus:
Andrew, that was perfect, thank you.

Andrew Schorr:
Okay. And you're 64 years old, and you're up the road from me. You're in Bellingham, Washington, on the road to Canada. What's your prostate cancer situation? Have you been, did you, have you had the access to this experimental vaccine in a trial, or was it something you had hoped would be available for you if it were approved?

Ted Girgus:
Well, at this point in time I am on hormones. I am an advanced prostate cancer patient, which means; prostate cancer likes bone, so, it is in my vertebrae and my pelvic region and other areas, and I'm on hormones, and I've been on hormones off and on since I have had my brachytherapy procedure, which unfortunately the cancer was outside the gland by that time.

Andrew Schorr:
Let me just explain that to people. So, there's a procedure done; it was actually developed here in Seattle, and you went to one of the doctors who developed it; where they can implant radioactive seeds in the prostate to try to give radiation directly to where the cancer is, but if the cancer has spread, and it's not always clear whether it has or not, then you need other therapy, and that's what Ted's talking about.

Ted Girgus:
Yes, and then Andrew, and I want people to be aware, to please go in for early detection. My PSA was low. It was 4, and my internist said, well let's move you along for a biopsy. But, you know, even though I had the biopsy and they did notify me that it was cancer, although I went for the procedure, the doctor told me, having cancer is like spilling a jar of salt. You could get all of the granules back in the salt shaker, but if you miss one, you lose. And I think that's part of what happened to me with the brachytherapy.

As a matter of fact, the doctor who performed the brachytherapy, Dr. Haakon Ragde, has since gone to the University of Manila because he was tired of fighting the FDA, and he is using a dendritic cell treatment very similar to Dendreon's, and he is having vast success with it, and anyone who wanted to travel; between the treatment and the travel and the stay, people are looking at $60,000, and it's hard to come up with that. I know your life is on the line, but it's hard for a lot of people to muster that kind of an income just to go for this treatment when we have it right here, you know, in front of us.

Andrew Schorr:
Right. Ted, let me ask you about this. So, here you are with this vaccine to help men with more advanced prostate cancer like you, and your FDA, your tax dollars, a, well thank you very much all you experts in the U.S., and we appreciate your vote, but we're not ready to move forward. How does that make you feel?

Ted Girgus:
You know, Andrew, more than anything, I mean, I'm 64. I have made peace with my god and I lay everything at his feet, but I have four sons, and I have nine grandsons, and the chances of them having prostate cancer because I have it are very high. You know, so, if it's for myself, yes, I would love to live as long as the next person and have a quality of life. One of my heroes is Eduardo Garcia, and I want to grow up to be just like Eduardo when I become an adult.

Andrew Schorr:
Yes.

Ted Girgus:
But again, the FDA, they look at statistics, and if they want statistics, we could give them some. Thirty thousand men die every year. Those are people like Ted and Eduardo, they're not just numbers. It's us, and we die, and our sons die, and our grandsons die. So, if they want statistics, there are some statistics for them. You know, if nothing else, they could have granted a conditional approval on Provenge, which would have allowed us to access it while they were gathering more statistics.

Andrew Schorr:
Now, we have to make another point too, and that is that a lot of the most innovative science in the last few years and certainly in cancer has been from biotech companies, not from big pharmaceutical companies. Not to put down Glaxo or Merck or Pfizer, certainly they do a lot of work, but it's companies like Dendreon or Genta that's been working on Genasense or some of the others, and so when the FDA, these companies raise hundreds of millions of dollars on a bet, you know, with Wall Street and earlier investment, trying to move to the goal line of having a product that they can sell. When the FDA delays approval, even when there's very positive data, it is really a blow to a smaller company like that, and so my concern is it cools off investment, and it also cools off the passion of scientists. They say, why have I been in the lab for all these years and then to have ice water thrown on us?

We're going to take a break in a minute, but I think that is something to think about. Is it not just a delay of Provenge, or as it was a vote against the drug that I thought could help in my condition in CLL, Genasense, but is it really cooling drug development that we all need? Congressmen, senators, anybody might develop a

serious illness in the years to come. So, it's a complicated issue, but there is lots to think about. We're going to take a short break, and then we'll be back, and we'll discuss this a lot more and get into it, and of course we welcome your calls on Patient Power as we talk about fighting the FDA for potentially life-lengthening and lifesaving drugs.

Andrew Schorr:
Welcome back to Patient Power. Hopefully I'm sounding a little better now. We're doing a lot of things behind the scenes to work on our technical connection. I'm way out here in Seattle, and we have people all across the country today. Mike, you're in New Jersey, right?

Mike Kearney:
That's correct, Andrew.

Andrew Schorr:
Okay. So, Mike, would you agree with what I said, that this is bigger than an approval or delays in a drug for men with advanced prostate cancer, but it's really issues on what the American public deserves when maybe they're at their sickest stage. It's a more global issue that we've got to fix with the FDA?

Mike Kearney:
That is correct. We depend on the FDA, and we have to make sure that they are serving the people, and unfortunately it's been questionable lately, and that's why we're challenging them because we think there are some political issues going on in the FDA. I mean, you've got some different divisions in there that they seem like maybe there's a power struggle, and then there's also some financial conflicts that we're questioning.

When you spoke earlier about testifying, you mentioned that the doctors that they had in there were people that were specialists, and they knew what they were talking about. Unfortunately, two of the most vocal doctors against Dendreon's Provenge, they're oncologists. They are in chemotherapy. They're not in immunotherapy, so there was a little lapse on their part as far as were they really two doctors that should be on the panel, and that's not even to mention the conflict of interest that they did have.

Andrew Schorr:
Well, let's mention something about that. You know, in fairness to the FDA, there are restrictions they work on in putting these panels together where they try very hard to have doctors on the advisory panels who don't have conflicts. Now, what does that mean? That means they don't own stock or maybe don't have a close business relationship with the company applying for approval. Okay, but think

about, like in my own condition in leukemia/CLL, it's not a common condition, so any drug company that is developing something is going to want the leading experts in the field to advise them and test their drug, etc. That's the way it works. Well, now we come time to approval, and if you have all the specialists for that illness prevented because of this conflict standard from being on the panel, then the doctors who are on the panel may either not be knowledgeable and/or they may have some other approaches that they believe in that they're financially invested in.

And so, for instance, as you talk about in this prostate cancer vaccine, it's not chemo. So, doctors who make money on infusion of chemo in their office, some oncologists do certainly, they think that this shot you could have would be a good thing, financially maybe not for them. So there are lots of issues behind the scenes.

Now, one of the things I wanted to ask you about, Mike, is there is a government official at the FDA, sort of the head guy when it comes to approvals related to cancer drugs, Dr. Richard Pastor, who is formally from MD Anderson Cancer Center, and I do a lot of work with them. And, he has been kind of a czar there, and he is named in your lawsuit. What do you think is going on with Dr. Pastor?

Mike Kearney:
Well, first we think it is part of the political struggle that is going on inside the FDA. We know that some people wanted Dr. Pastor to be the commissioner, now whether this is behind what he is trying to do I'm not sure. We know he was very active at the advisory panel, and we just don't understand if they called the panel and the panel says, listen, this is safe and it shows evidence that it works, even with the dissenting doctors votes, what's the delay?

The other part of the issue is that some people released some information. To us, the FDA should have been keeping everything under wraps while it was considering a decision, but some information went out on the internet. It was made public, and it really brought into question why are these people so anxious to get out there and fight against this, and then as we all started looking at it and uncovering statements for these folks and other competitive drugs that they are working on. And we're going to try to get to the bottom of it.

Andrew Schorr:
Well, that would be good. You know, we've got a question on exactly that. Nick from Portland sent an e-mail, he is listening, and he said, when the FDA overrules an advisory committee panel for treatment of a terminal illness, as in the case of Provenge, shouldn't the FDA be mandated to provided full transparency on why? For starters, which FDA members voted to overrule and their arguments, similar to a Supreme Court ruling, you know, really in detail. And that's what we don't get, so

it sort of seems like a hidden agenda, and they just say, more data, more data. And the other thing that I have noticed, and I certainly saw this with Genasense is when you have new kinds of medicines, and in the case of Provenge we are talking about anti-cancer vaccine, and again folks, this isn't a shot you get to prevent you from developing prostate cancer, it's to marshall your immune system to fight the prostate cancer you already have where your immune system had not done that job the first time around. And, so, these cancer vaccines are a whole new approach and so understanding they want to dot their I's and cross their T's but folks like Ted are worried about dying in the meantime, and as you said for your sons Ted, you know, is this going to continue to work this way and deny them maybe the treatment they need.

Ted, let me ask you, have you gone to any congressman or senator yourself or written any letters? Because it's gotta make you angry.

Ted Girgus:
It does indeed, Andrew, and I have indeed. Thanks to the help of the community over the internet that we have, I was able to get the addresses and e-mails of certain congressmen, senators, and even journalists to try to get them involved in the fray, and there has been no response. Our congressmen, they don't even have an automatic e-mail response that says, we're in receipt of your e-mail. I mean, it just goes into this black hole and nothing. So, you know, I wrote to my congressman. I wrote to both senators in the state of Washington, and I e-mailed the FDA just asking for an explanation. You know, and you mentioned earlier, Andrew, you know this isn't just about Provenge and my life. I mean, 30,000 men each year die from this, and die a horrible death by the way, and the only option right now is chemo, and chemo is not effective. And I don't know if people realize, but chemo was derived from mustard gas that they used in World War I. I mean, it's a poison. It's a highly toxic substance, but because of the delay to Provenge and the biotech communities at large, Dendreon had to shelve their Neuvenge, which their phase-1 study against breast cancer; it just came out in the Journal of Clinical Oncology; that it shows positive results, but Dendreon because it was stifled had to shelve their work on Neuvenge. So, it's a snowball that's rolling down hill, and it becomes this giant avalanche unfortunately.

Andrew Schorr:
Right, and as I said, you know, if you're a scientist; let's say that you were the scientist who's working on Neuvenge, and the CEO of Dendreon comes in and says, you know, we just don't have the bucks we can put in this. We're going to continue the fight with Provenge, which is further along, which is great that they can even attempt to do that. Then, you just say, gee, am I in the wrong business? I'm passionate about helping people fight cancer or other illnesses, and yet the roadblocks are just too high, and I'm going to do something else. And that would

be a tragedy for our country, and of course these are drugs that are developed for worldwide use, and so it's such a shame.

So, let me go back to Mike. Mike, where are we now? You have a lawsuit. What are you asking for? Are you asking approve the drugs or make them available for people in later stage illness like Ted, or allow Eduardo to keep getting it? Where are we with this?

Mike Kearney:
Okay, the gist of the suit is we want the FDA to give proper due process to Provenge, which we feel like it did not do. And we just want to know why doesn't the FDA just do as we request? They know about the conflict of interest and reconsider with undue influence from Dr. Pastor. It's just so simple to reconsider and give Provenge due process as required by the U.S. Constitution. We want to do this fast, immediate, and we just want them to straighten out what they didn't do the first time; give Provenge due process, let this thing go through the way it's supposed to, and do it now.

Andrew Schorr:
Now, let's give information to people how they can participate. So, your web site is caretolive.com is that right, Mike?

Mike Kearney:
That is correct. And we are for prostate cancer patients.

Andrew Schorr:
And is that the best way people can get involved?

Mike Kearney:
Yes. They can go to the caretolive.com web site. They can click on the membership form link, and we urge prostate cancer patients and breast cancer patients. Dendreon just had a nice press release on Friday about how Neuvenge did in phase 1. They also said that what they're doing with the breast cancer treatment, they may be able to use the same things with ovarian cancer and colon cancer. So, when the FDA stopped Provenge, we know it hurt the Dendreon Corporation because Dendreon doesn't have a product on the market, so it has no dependable revenue, and it stopped Neuvenge, and now it's stopping ovarian cancer research and colon cancer and whatever other cancers. And chemotherapy may have some good parts of it because it has helped some people, but chemotherapy destroys the good cells along with the bad cells, where immunotherapy builds your immune systems so the good cells go fight the bad cells, and that's why we're behind this kind of treatment. I mean, it's just so good for mankind. And so Care to Live is going to stay after it until we can get Provenge to the gentlemen now and get the breast cancer

treatment advanced and just keep on pushing for it. It's like our name says, we care to live, and Eduardo is a great example of this and how is he living life to the fullest, and we want to help Ted, and this is what it's all about.

Andrew Schorr:
Eduardo, so you must listen to what Mike is saying and Ted as a younger man, and you must be extremely supportive of this effort.

Eduardo Garcia:
Definitely yes. I think this is the right way to do it. My opinion is that if the Food and Drug Administration approved chemo 30 years ago, which has definitely not proved to cure anybody, and it does, you know, you lose your hair, you feel terrible, and your way of life completely changes. Anybody who took chemo is not the same person after that, which is completely different if you take Provenge. You know, when you take it, the reaction is so mild, like if you have a very mild cold, you know. And then, after awhile you start feeling the energy. Now, I have bone cancer, and every three months my doctor sends me, and every time he measured, and he…

Andrew Schorr:
You have a bone scan, yes.

Eduardo Garcia:
…congratulated me because that cancer is still there. It's in my hips. It's in some of my bones in my back, but it has not gone out to the rest of the things. And the main thing, the most important thing is, I have no pains, and I can move. Right now I am doing exercises. I went to a gym, and I do exercises on certain machines, you know, with the bicycles and stuff like that. So, at 82 years old, I think that's excellent, you know, to have that much.

Andrew Schorr:
I'm amazed.

Eduardo Garcia:
So, this is my opinion.

Andrew Schorr:
I'm amazed. So, here's the thing is, I would mention to folks if you search a blog I've done on healthtalk.com, which is a web site I founded before patientpower.info. If you look at my blog, you'll see I wrote about this a lot, and I was quite angry after I attended that FDA oncology drug advisory committee hearing last September, and so I went on for weeks about it, and now it's sort of getting rekindled, and it really makes me feel great to connect with you gentleman

and our listeners today, because as you said Ted, we haven't been getting the attention of the elected officials, yet they're the ones who approve the budget for the FDA, they're the employers of Dr. Pastor, of Dr. von Eschenbach, who is head of the FDA. He used to be head of the National Cancer Institute. So, here we are, very important people, but they need to answer to Congress, and Congress needs to answer to us. So, I think about it. If one of most powerful senators gets cancer and finds out tomorrow that they have advanced prostate cancer, won't they want something like this available to them? And if they or their office calls and says, hey, what's the problem? You know, they're going to see what we've all been facing. It's extremely frustrating. Mike, do you think we have a chance? What do we need to do to move this mountain?

Mike Kearney:
I'm sorry. Andrew, could you repeat that?

Andrew Schorr:
Yes, I was saying, what do you think we need to do to move this mountain? Because it seems daunting. You feel like you can't fight city hall. We've talked about how the FDA is not transparent to somebody. One of our listeners said we wish they would explain all their reasoning. How do we move this mountain?

Mike Kearney:
Okay. First of all, we encourage as many people as possible to go to the rally on September 18th at the FDA. You can access this information on caretolive.com. There is another web site call arighttolive.com. We believe we can prove all the assertions that we made in our pending case against the FDA. And so we're going to pursue that, and we are going to challenge them, and we also would like to ask Congress to get involved and look at making some changes at the FDA even with policy. Even two of the doctors that were so vehemently against Provenge, one of them was quoted not too long ago saying even the slight benefits are significant in a tough disease. Well, this is a tough disease. And then the other doctor said it may be time we focus less on statistical significance alone and more on patient benefit. So, if these doctors believe this, and then they see the safely of Provenge, what's the problem?

But to answer your question, Andrew, we are going to keep pursing it. We're pursuing the lawsuit, and we're pursuing to see if we can get some changes inside the FDA to help the American people. I mean, a lot of this stuff is so common sense. I explained it to a third grader. I said, look, here's what happened, and you explain what immunotherapy does, and they get it. We just don't know why the FDA didn't get it.

Andrew Schorr:
Right .Well, I want to help you, and again just a word about immunotherapy if people are not up on it. And the idea was, is that your immune system did not recognize these defective cells that your own body was creating. That's what cancer is. And so, the idea is to convince your immune system that it can do better and help it do that, and that's the whole idea of cancer vaccines where otherwise chemotherapy is typically just looking for cells that are dividing and not dying and just kind of wipe them out, and it causes the collateral damage we talked about; hair loss and nausea and fatigue, etc. And so, that's why these targeted immunotherapies are so promising, but there have been a lot of road blocks to so many of them and certainly from some of the smaller biotech companies. Not always, but here's an example, and it's very frustrating.

We did get a comment in from Steven who wrote, guess what Ted? He wrote, we're on our way to Manila since my dad can't get Provenge here in the states. And as he says, it's just so sad. So Ted, there's a guy who knows whether they are wealthy or not using what dollars they have to go to where I guess Dr. Ragde is now to get what they believe has promise but can't be approved by our own government. So, pretty frustrating.

Let me mention these web sites again. So, there is caretolive.com, and that's the one founded by Mike, and then there is also arighttolive.com, and they've been organizing this rally. This rally we've been talking about is September 18th from 10:00 a.m. to 12:00 noon Eastern time right there at the FDA, 5600 Fishers Lane, Rockville, Maryland, and the idea is to get cancer survivors and family members there, parade around so the FDA sees, but most importantly bring the attention of the press.

Now, I wanted to ask Mike one question. You know, we get approached a lot of times by public relations people, and there are some very good ones, but usually they are representing some commercial interest trying to advance sales for that product, medical product, whatever. Sure, if Provenge was approved, that would help Dendreon and its investors a lot. But that's not what we're talking about, and what I get from you Mike, and Ted and Eduardo, is it's just us patients trying to have our government do what's right. Would you agree?

Mike Kearney:
Absolutely Andrew. That's absolutely what we're hoping for. It's time to turn a page in cancer treatment. Immunotherapy is the new thing, and Provenge is demonstrated to be safe in more than six clinical trials, the most common complaint was two-four days of flu-like symptoms, like Eduardo told us, and the people are living four and a half months longer on average than the current treatment of Taxotere, which is the chemotherapy, and sometimes we're amazed

that the chemotherapies ever got approved because if we can't get immunotherapy, which is safer and a better immune system instead of a chemotherapy, which is also destroying the good cells, we just say, wow, what's going on here? So, it's just basic common sense.

Andrew Schorr:
I do a lot in cancer, so I just want to mention and I want to be fair to chemotherapy too.

Mike Kearney:
Sure, sure.

Andrew Schorr:
So, I benefited from a monoclonal antibody, an immunotherapy in a way, being combined with chemotherapy. And many of the cancer doctors think at least for the next little while, there will be these sorts of combinations.

Mike Kearney:
Right. We've seen a cycle where Provenge was given and Taxotere and then a Provenge booster, and we've seen better results with that. But we got Taxotere out there; let's get Provenge out there now so we can do these kinds of treatments where they are showing good results.

Andrew Schorr:
Right, right. Well, I wish you well with the rally. Unfortunately, it may take a senator or a senator's spouse or somebody like that to find themselves in the same boat that Ted's in to say, hey, what's going on, and for them to be chairman of some committee that approves the budget for the FDA. I'm not sure, you know, I wish you well with your lawsuit, and I hope it goes well.

We'll discuss this more, and I hope you will keep us updated on the progress, but I urge people to go to the caretolive.com web site, and if you can, if you're anywhere near Washington D.C. and you're affected by all this, you know, just like we've had other marches on Washington, have a march on the FDA September 18th, 10:00 a.m. to 12:00 noon right where the FDA office are at 5600 Fishers Lane, Rockville, Maryland, right outside Washington D.C.

Oh boy. Well, I think we can make a difference. Mike, I want to give you a lot of credit for what you're doing and just really wish you all the best. Ted, do you think this can make a difference?

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Ted Girgus:
You know what? We need to learn from what the HIV people did. We need to make some noise. We do not want to go quietly into that good night, Andrew. So we just need to make some noise and get people's attention because we've got something worth hollering about.

Andrew Schorr:
Right. We sure do. Best to all of you. As always, knowledge can be the best medicine of all. Good luck guys.

Ted Girgus, Mike Kearney, Eduardo Garcia:
Thank you Andrew. Thank you for all you do. Thank you Andrew.

Andrew Schorr:
Thank you. Thanks gentleman.