



Patient Power

CLL: Where We Have Been and Looking to the Future

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Andrew Schorr:

Hello, it's Andrew Schorr from Patient Power and I am delighted to connect with my savior, I think, I think he saved my life, Dr. Michael Keating at MD Anderson in Houston. Hello, Dr. Keating, thank you for being with us.

Dr. Keating:

It's great to catch up with old friends. That's one of the things about CLL that the patients hang around with you for such a long time, it's inevitable that you become friends. You're a couple of my best ever.

Andrew Schorr:

Thank you! So, I'll just mention it was in 1996 when I first met you. Terrified, I'd never been to Houston, I lived in Seattle, was recommended to come down there by other patients, "Granny Barb" Lackritz from St. Louis, one of your patients who ran an internet list, she said go see Dr. Keating, and your secretary, Sabrina Harris, a wonderful woman. You told me to chill out and that I would be in the watch and wait time for a while, which I was for four and a half years.

As things progressed, you said maybe we ought to take another look at you, and that led to me being in the FCR Phase II trial, which you put together and it became a worldwide standard. You know that besides you giving hugs, that FCR combination made a huge difference to people worldwide. That must be very satisfying.

Dr. Keating:

It is very satisfying, but I still keep on telling patients we aren't finished yet. I've still got to make it kinder and gentler and even more effective and have realistic expectations of a number of patients being cured of the disease.

Andrew Schorr:

Well, you and I spoke in 1996, we did a program with Dr. Kanti Rai, famous in CLL of course, and you talked about how you really wanted to push for a cure. So, when you say you're not finished, that's where we still have to go, right?

Dr. Keating:

Yes, and actually Wierda is leading the charge on that with a number of these new therapies and measurements of residual disease.

Andrew Schorr:

Well, just yesterday as we were recording this, there was yet another CLL drug approved, acalabrutinib, and there's been a succession of approvals. So, you must feel good about that. Where you used to have not much, now there are many options and the prospect of exciting combinations, right?

Dr. Keating:

Indeed. I think that one of our challenges now is to fine-tune to protocols and make them as financially accessible as possible because all the new drugs are very expensive. So, the more we can get it down to exactly the right dose and schedule, the more value we'll be able to offer the people.

Andrew Schorr:

So, Dr. Keating, besides folks like me seeing you in the clinic, you've really propelled fundraising and research. So, let's talk about the CLL Global Research Foundation. It was with patients that you founded that and I think it's something like \$26 million in research grants have been made often to younger physicians as well, you mentioned Dr. Wierda, but people who were doing research that you thought could pay off. You must be very satisfied with that.

Dr. Keating:

One of the very nice things about the global research is if we find someone who's better at a laboratory program or testing something, it would take longer for us to start up and catch up to them. So, it's a lot more efficient for us to make donations to them. We meet together and they're evaluated by a person at Anderson and someone outside the Anderson to check on no conflicts of interest, etcetera and the truth coming out.

So, yes, I think we hit \$26 or \$27 million and it includes people from Europe and people from Canada and the U.S., Australia, and a number of different places. We try and make it as efficient as we can because I think so many of us know where the advances are occurring. Instead of just opening up for anyone to apply, we have selected labs and investigators so that we don't end up with having four-day evaluations and a lot of wasted time.

Andrew Schorr:

Well, let's talk about another benefit, and I think you kind of alluded to this, in some areas of medicine, traditionally, the doctors, the researchers didn't really work together. They were very competitive. I think one of the things you facilitated with CLL Global Research Foundation is a community of researchers, wouldn't you say, and they collaborate.

Dr. Keating:

They do. We have a meeting coming up now that's called The Alliance and these are people that we've worked with over the years and shared our data. A few years ago, one of the local celebrities in Houston, Bob McNair, has an institute and he told us the thing that stands him is this competitive thing and redundancy with people doing the same thing and not sharing their data with the fear that it would be taken from.

We're able to get around that by the people that you pick and I have this saying that they have to be committed, they have to be humble, that is they know where they are in the whole fabric of things, they have to have more than a touch of altruism, and they have to be trustworthy. People that have those characteristics, I think, love working together.

Andrew Schorr:

Well, it's been a great thing and I've met many of them. One of the things that I think is exciting to those of us living with CLL if we haven't cured it yet is that there are younger physicians who are attracted to the field and are joining in. So, while you feel there's unfinished business, you must, at this point in your life, still take some comfort that there are pretty smart younger people who are working on it.

Dr. Keating:

Yes, indeed. One of the things that we do from the foundation is we ask people that we know and trust and they select young doctors that are interested in CLL and hematology and they compete for the position where they come over to MD Anderson for a three-year period and it's mandatory that they go back to their own country of origin because America has a habit of poaching talent from less fortunate countries. So, we have a number of our people that have gone back that have had leadership roles now in programs in different parts of the world.

Just recently, we had our first young doctor, a young woman from Russia. I think that it's nice if enemies, so-called, can work together in good causes and find out that just because they come from a certain place or have a political persuasion, they're not bad people. They're just people that want to do something good for mankind.

Andrew Schorr:

Dr. Keating, let's talk about your career a little bit. When you started, most people with leukemia didn't live very long.

Dr. Keating:

That's correct.

Andrew Schorr:

Based on your work and the work of some of your peers, you see people like me 23 years after diagnosis. What's it been like for you to, as you say, really develop relationships with people over the years based on the medical treatments that have been effective? You've given a lot of hugs and a lot of hugs to the same people over decades.

Dr. Keating:

It's actually wonderful because there's a vulnerability that comes with being diagnosed with leukemia. People are afraid and they want to talk to someone and you have to build up that trust because it doesn't matter how powerful and how wealthy they are, leukemia is a great evener. They carry their fears and apprehension with them. I've been very, very fortunate that the people that have worked with me in the clinic, the doctors, the nurses like Alison, Jackie Broadway, and Sabrina. My AA, Sabrina, if I come and want something in a hurry, she'll say sorry, doctor, I can't talk to you now. I'm talking to a patient. It's very nice that she sets our priorities like that.

Andrew Schorr:

Everybody's done that but you've done that, Dr. Keating. You've gone more than the extra mile for people. I've been at conferences with you around the world. You've made it your mission to speak about it. You've been so devoted, I can't imagine how you have enough hours in the day.

Dr. Keating:

Well, my family has been discussing that, how I was absent for so many periods of their life and that's one of the conflicts that we all have. There's a very serious issue in medicine these days with burnout because everyone's cutting costs and expecting people to do more with the same budgets, etcetera. This is where the foundation comes in. We can actually ease those burdens a lot by propitious use of the donations from our patients. Most of them are patients that have been around for a long time and been followed by Dr. Wierda and myself and others, etcetera. They expressed their gratitude in the nicest possible way and investing in their future and the future of patients with their disease.

There's always an anxiety because there is a familiar element to chronic lymphocytic leukemia. It's a leukemia which is more likely to occur in families. So, one of the things we have to assuage their fears by telling them how relatively infrequent it is and what we can do to diagnose it at the right time and treat it at the right time, etcetera. So, I think that a number of families like to invest in the possibility that we'll learn something that might prevent their family members from getting leukemia or other cancers and I think one of the projects that we'll invest in this year will be a new method of early detection of specifically.

Andrew Schorr:

Dr. Keating, let's just go over in the high level what we've learned about CLL. So, years ago, we knew it was a chronic leukemia versus an acute leukemia, but we began to understand much more about the cell, what could kill it, what could hold it back, how it reacted with other cells. Just take us through that briefly about sort of peeling back the onion to understand CLL.

Dr. Keating:

Well, I think the thing was when we could quantitate proteins on the surface of a cell so that some diseases that look like CLL were not CLL and by flow cytometry, we could sort of these outliers and give them very specific treatment for that. I think there was tremendous advances when we were looking at the mutations in the immunoglobulin gene and a protein called lipoprotein, lipase, etcetera. They gave us insight into patients that behaved well and those that behaved less well.

Also, the discovery of chromosome aberrations that were characteristic like loss of a portion of chromosome 13 where they have these little non-coding genes called miRNAs, which were discovered by Carlo Croce and George Calin. This is a very, very active area of research at the present time, continuing on so that we can now specify the subtypes of CLL and we've become very aware that the cells are driven by what they call a B-cell receptor. This is where drugs like ibrutinib (Imbruvica) and acalabrutinib (Calquence) have come along and learned that the cells are very long-lived and they are long-lived because they have very high levels of a protein called Bcl-2.

Bcl-2 is now inhibited by a new drug called venetoclax (Venclexta), which was actually developed down in Australia at the Walter and Eliza Hall Institute and two of the three authors on the first publications were from the CLL Global program. They came over to MD Anderson from Australia and spent three years and had then gone back. So, Dr. Constantine Tam and Dr. John Seymour took it back and worked with the Biologic Institute at Walter and Eliza Hall. So, I think one of the great things has been that we excited interest in studying the biology of the CLL cells and from that, we learned to apply many of the concepts to other leukemias and other cancers.

When I tried to get one of the MD Anderson fellows to work on CLL, he said nah, it's the most boring disease on the planet and no one ever gets to be famous working on that. The good thing that he didn't say rich. That was when I was being replaced in the acute leukemia program and I had to find something to do. So, these other guys weren't interested in CLL so I said well, we're not doing very good research on that here, so I might as well see if we can do something a little bit different.

Andrew Schorr:

Well, you have! Let's talk about that. When you reflect on that decision, that where other physicians were going into more exciting areas, you went into what they said was a boring area. You have helped yourself or propel a big difference. Here I am and other people living a long time. How do you feel about it, Michael? How do you feel about it?

Dr. Keating:

I feel fabulous. I have been blessed by one of the great mentors of all time, Dr. Freireich, who was the first to cure childhood leukemia. He developed this model of research where the clinicians had to learn about the biology and the people that were doing the lab research had to come to meetings and learn about the disease. That has continued ever since and I think it's the translational research and having very close interactions between the scientists.

I just met one of the people that started with Dr. Freireich. He's a statistician. He's now in an assisted living complex, Dr. Gehan, and the way Dr. Freireich went about picking out the statistician to work with it, they were at the National Cancer Institute and Dr. Zoobra thought it would be good for the clinicians to present to the statisticians so the statisticians could figure out how they could play a role in the research. I said how did you pick Dr. Gehan and he said he was the only statistician that didn't fall asleep when the doctors were talking and we used one of his statistical tests, the Gehan-Wilcoxon test to measure survival and differences between groups.

So, Dr. Freireich brought that down and I think made MD Anderson famous by having this close interaction between MDs and PhDs. It's a model that I think bears copying everywhere around the world.

Andrew Schorr:

Dr. Keating, let me ask you about just like Dr. Freireich with acute leukemias, you and chronic leukemia, you're kind of at a point now where you're passing on the baton.

Dr. Keating:

Yes.

Andrew Schorr:

How do you feel about that?

Dr. Keating:

I feel nervous every time I see a relay race and see when they bungle the handover. I say we've got to get this right. The fabulous thing is that Bill Wierda, who did his Ph.D. and a lot of interactive work with Tom Kipps, who had the CLL program

project grant over in San Diego, Bill, when he came over to here, had some amplification of the clinical experience to go along with the Ph.D. So, if you look at the relay race analogy, I'm plotting from not being the fastest anymore but I know that I have the baton receiver deluxe, that I can hand it over to Bill and he believes in the same sort of concepts.

At the moment, a number of the younger folk, for example, Bill has been mentoring Dr. Nitin Jain, who recently published in the New England Journal of Medicine a combination of two oral medications so you don't have any IVs. The toxicity is very manageable with these two things so patients who go onto treatment for a year or two with these drugs, more than 95 percent of them will get a complete remission of the disease. As they get more courses administered, more than 50 percent of them, we can't find a single CLL cell through a detection level of 1 in 100,000.

Now, can we say they're cured? No, we can't because we have some people that have had CLL and have never been treated that will leave 10, 15, 20 years and they have very slow-moving disease. So, statistically, you can't say I have proven, but it would be highly suspicious that a very significant number of people are being cured at the present time. So, I think our job is to bring along more of these very effective relatively low-toxicity programs and offer them.

Now, one of the good things is while they're very expensive either singly or together, many of the national programs in different countries have realized that the results are so good that they will cover them so that insurance will often cover them. One of the examples that I will use of the collaboration with research was that I was suspicious that some of the side effects of one of the drugs, ibrutinib, it's a very well-tolerated drug by and large, but the recommended dose was three capsules a day and I thought it might be too much.

It attaches to the B-cell receptor and Dr. Varsha Gandhi, who comes through leukemia with Dr. Bill Plunkett, she found that you could be complete attachment with only one capsule rather than three. So, that dropped the price down from \$12,000 a month to \$4,000 a month. Now, this has led to a comparative study up in Canada by the National Health comparing three to one to see if we can make it a worldwide standard again. So, I think that it's not sexy science, but boy, the patients love the fact that they don't have to fight for the insurance coverage all the time.

You know, a lot of people probably don't know this about you, but together with the inspiration of "Granny Barb" Lackritz, you have written a book about questions that you need to ask if you have CLL and that translates to questions that you should ask if you have a diagnosis of any leukemia or any cancer and where to get accurate and timely and current information. I have recommended this to almost every patient that comes to see me and they pass it on. I think it's a fabulous model for a patient to actually develop a patient-friendly resource like this because when I recently underwent hospitalizations for things, etcetera., even being a doctor and my wife being a very smart lady, we didn't know much about brain problems.

So, I've actually recommended that someone from the neurology clinics around the Texas Medical Center get copies of your book and then contact you so that we can set up information tanks like that for common diseases that people can maximize the benefit from what they've invested in their retirements and their insurance policies and things like that.

Andrew Schorr:

Well, Michael, thank you.

Dr. Keating:

You have made a very big difference to a large number of people in your life. You've been quite a baton-taker yourself because the patients have developed this into a sharing modality.

Andrew Schorr:

Well, thank you, I'm touched. I think for you and for me, it's about paying it forward. Before we meet young Dr. Wierda, as I call him, I just want to ask you, Michael, you alluded to some time in the hospital. The patients around the world who know you want to know how you're feeling. How are you doing?

Dr. Keating:

I'm actually doing very, very well. Just for information, a bit over a year ago, I had a small stroke with limited my vision and still limits it looking to the left. After that, I had to have back surgery and when they dropped the anti-clotting medication, I

developed a larger stroke. So, I've been sort of in-patient and outpatient and in hospitals and doing rehab pretty much for about 15 months. I can now walk without assistance, although everyone wants me to be ultra-safe and use a walking stick or a walker.

Also, you have to retrain your memory so this has been a big challenge to me because I don't want to take any risks recommending treatments and testing on people if my memory is not as good as it was. I can't do things as quickly, so I haven't been doing first in line patient care now for over a year because of the ultra-conservative nature of people recovery from strokes. They didn't want me to come even into the Anderson building for over a year. So, now I'm back and Bill and I are working to see what remaining talents I have can be put to good use. So, I'm going to be slower than I was, but there's always something that the turtle can do that fits into the whole game plan.

I think that the patients that come along to the clinics, we'll probably have sort of as an extension of patient power, all the patients that come on the first week of the month, for example, we may have an opportunity to just talk to them about CLL when they're waiting for their marrow results or their blood test results and then the second week, we'll do something different, and the third week and the fourth week. So, we're hoping that you will participate in that and load then on so that we can keep the information as current as we can.

CLL is not just a disease that involves the patient and their family and doctors and nurses. It's corny to say it takes a village to raise a child, but it takes a whole bunch of people to give the very best opportunity for long-term survival and control. Dr. Ferrajoli is setting up a survivorship clinic where we'll not only be measuring continued improvement but Bill, in particular, is very interested in looking at the immune system of patients that have been free of disease for as long as you and find out if we can restore that to normal.

One of the other things is the tech thing, other cancers that occur in CLL like skin cancer and melanoma and some acute leukemias early so that we can limit the extent of other therapies that we have to do. One of the things that did impress me was that patients die of things that patients without CLL die of. They die of heart attacks and strokes. So, we'll be measuring their cholesterol and their lipids and making sure that their blood pressure is under control.

The other thing that occurs in people that are older, and the average age of diagnosis in CLL is in the early 70s, is actually falls. So, I've spoken to the rehab people in the medical center and we'll be offering evaluation of fall risk, how the balance is, and then have a program to improve that balance so that people aren't falling over and breaking hips and pelvises and things like that because we just want everyone to live as long and as well. There was a quote that I read, 'It's not so much how long you live, it's how much life you live in the years that you live.' So, we want people to live as normal a life we possibly can.

You're just a striking example in how you've gone about doing that. You're one of the people that I would like to have inducted into a CLL hall of fame if we ever have one and "Granny Barb" posthumously because she would still be alive now if she were diagnosed five years later.

Andrew Schorr:

Thank you so much for that. We're all trying to pay it forward. So, let's meet a young man, you're referred to him several times, Dr. Bill Wierda. Bill, you're there somewhere. Can you come sit down, pull up a chair, move the computer a little so get you both. There we go. So, Dr. Keating, you've been referring a lot to Bill Wierda, M.D., Ph.D., came from the West Coast, came to Houston, and now really you've mentored him with the CLL Global Research Foundation and I think, Bill, you're also the medical director, right, for the Department of Leukemia, is that right, at MD Anderson?

Dr. Wierda:

Yes.

Andrew Schorr:

So, we talked with Dr. Keating about the passing of the baton and he was saying he's not running quite as fast as he did. You're still in a position to run faster. How do you feel about carrying on and what are you excited about doing?

Dr. Wierda:

So, I came here back in 2001. Dr. Keating recruited me. At the time, I was working with Dr. Kipps and at the time, I felt like I needed to come here because it was an opportunity of a lifetime and I would regret had I not come here. Certainly, I have not been disappointed. Dr. Keating, over the 19 years that I've been here, has been extremely generous with his intellect. He is an extremely generous person. We've worked together on our CLL clinical trials and patient care for years and I still feel like I have a lot to learn from Dr. Keating.

He has remarkable insights and I frequently will say that he is one person in my life that I have known that I can always go to to look for a new idea. So, he is never at a loss for a new idea, coming up with something new, thinking about some things in a new perspective, and I think that's important for developing new treatments for patients with cancer and really for any scientific and medical efforts. I still have a lot to learn from Dr. Keating and he has tremendous insights into the disease and has seen a remarkable history of improvement in therapy for patients with CLL.

As he was mentioning, we've done a lot of work recently with combinations of the small molecule inhibitors and we're getting patients into very good deep remissions. Most of our patients are now achieving deep remissions. I have never had more patients than I have now who've been on treatment and are MRD negative and in fact, I probably spend more time in the clinic now talking about health maintenance things, survivorship things, than actually treatment for CLL because our patients are doing so well and they're in remission.

So, it's been a very exciting time. We've seen remarkable progress in therapies for CLL. I think now we need to focus our attention on, as Dr. Keating was saying, immune function, quality of life, preventing the things that can be problems for our patients like second cancers and infections.

Andrew Schorr:

So, Dr. Keating and Dr. Rai did an interview with me in 1996 and Dr. Keating said I'm going to keep going. I am out to cure this. Now, Dr. Keating, you're not stopping. You're going to be very visible around, but still, you said it yourself, while there's some people who may be cured, we can't universally say people are cured. Now, Dr. Wierda, you're talking about immuno-approaches and cancer developed when our immune system kind of let us down and we started creating these defective cells. Where do you think we are? Can we really have the prospect of a real cure where either we prevent CLL or our immune system zaps it?

Dr. Wierda:

I think we're on the verge of that. To some extent, for many people, I would consider them in kind of a cured category where they may need treatment, but we can control their disease and manage their disease and not have their lifespan shortened by having the diagnosis of CLL. But again, we need to work on some of these other things that can cause problems for those patients like infections and second cancers, having a better understanding of the immune system and immune function and then having ways to intervene and correct the immune deficiencies that patients who are a unique group with a diagnosis that causes immune function unlike other diagnoses of cancer.

CLL is a unique situation and a unique diagnosis and that's actually why I was interested in the disease from the very beginning.

Andrew Schorr:

Let's talk about uniqueness for a minute. So, Dr. Keating, in describing earlier the increasing understanding of CLL was the understanding of chromosomal abnormalities that could vary by patient or either vary by time, so that brings up to personalized medicine. Probably when you started, Dr. Keating, it was a one-size-fits-all, CLL was CLL was CLL. Now, Dr. Wierda, you evaluate people and see what version of CLL they have, not just what version of CLL, but what version of CLL they have at that moment, which could change. So, that's been probably one of the most exciting at least interim approaches, is very personalized approaches for what version of CLL you have and having the tools to do something about it. Maybe you could elaborate.

Dr. Wierda:

We know more about the genetic abnormalities and the chromosome abnormalities and in fact, as you say, we do personalize treatment. For example, patients who are younger who can tolerate FCR, we know from Dr. Keating's work over the years and the long-term follow-up we have, patients who have a mutated immunoglobulin gene and receive FCR, about 50 percent, a little more than 50 percent of them maintain their remission more than 10 years and are probably cured. So, that's a particular group that we've identified that benefits from chemotherapy, chemoimmunotherapy. We're working on clinical trials to continue that and improve the outcomes that we have for that particular group of patients with a modified version of the FCR regimen where we're including ibrutinib and obinutuzumab (Gazyva).

Andrew Schorr:

Then, you're working on combinations that don't include any chemo, just oral therapies or sometimes with a monoclonal antibody. Dr. Keating has talked about how do we manage the cost, but powerful new medicines that could give sort of a bigger bang, right?

Dr. Wierda:

Right. With our combinations, if you think about it, if we talk about one-year or two-year fixed duration treatment, even if we're using two or three drugs and we can get a remission that lasts four, five, six, seven years, that's probably better than having patients on an individual drug for that whole duration of time where cost is an issue and also side effects and toxicities and challenges that we have with those drugs can arise during that time the patients are on treatment.

Andrew Schorr:

Okay, just a couple more things. CLL Global Research Foundation, where is it headed and Bill, from your point of view because you're going to carry on here a lot, so what's your goal?

Dr. Wierda:

My goal is to partner with Dr. Keating. He started the foundation, he's still, as you can see, as vibrant and as thinking about the disease and thinking about what our clinical and scientific priorities are. So, I feel like I need to partner with Dr. Keating to make sure that vision moves forward and we can continue that. That will require additional work in terms of fundraising and development, things like that, but my goal would be to partner with Dr. Keating to make sure the vision continues. I have benefited from the Global Foundation when we were working on some of the earlier work. My colleagues here at MD Anderson, my clinical and scientific colleagues around the world have really benefitted from the foundation. So, I think we need to make sure that that continues and that vision that Dr. Keating developed several years ago continues and potentially even accelerates because there still is a need for work and research and progress in CLL.

Andrew Schorr:

Amen. Michael, was there something you wanted to add?

Dr. Keating:

Yeah, I think that one of the things we'll be having a meeting of local and national and international people in January and we'll send out a report on new relationships that get developed along the way. It's really nice that Kanti Rai is coming down for that meeting. He's like the Eveready Bunny, just keeps on ticking, and it's he's getting better than ever. One of the things that illustrates the importance of the clinician and the scientist is Kanti's relationship with Nick Chiorazzi who runs the Feinstein Institute up in Long Island. They've now changed the name there.

Nick was one of the first people to talk about the mutation status of the immunoglobulin gene and he is still very passionate. So, the two of them are coming down with some new ideas. I remember we had Kanti down for one weekend and there was a really high-powered talk that was being given so Nick said to Kanti we might as well fill in some time and go to that. So, Kanti, at the end of the talk, they said any questions and there were very few because it was very high-level. Kanti just stood up and asked two or three very key questions. One of these days, I might surprise myself and find instead of Bill taking the baton, Kanti will be still be running.

Andrew Schorr:

At 100 years old, right! I just want to say from the patient perspective, and I know I speak for people around the world, we want to thank you, Michael Keating. You've helped write, for sure, rewrite, carrying on from Dr. Rai, the natural history of CLL. I'm an example. We are totally indebted to you. Dr. Bill Wierda, you're going to write new chapters in the history and your younger physicians around the world and you're so devoted to working together, we really appreciate that, and with leadership from this foundation that was started in partnership with patients, CLL Global, thank you both for all you do. I just want you to know we're very grateful with how much – Dr. Keating, we wish you a long life, good health, clear thinking, and a steady walk.

Dr. Keating:

Okay, I'll do my best.

Andrew Schorr:

Thank you. Andrew Schorr with Patient Power with two generations of the CLL Global Research Foundation and really the past, the present, and the future for CLL. Remember knowledge can be the best medicine of all and our partnership with folks like this.

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