**EPISODE FOURTEEN:**   
  
Bringing the Payer and Provider Perspectives Together:   
Dr. Lee Newcomer Shares His Unique Take on Precision Oncology

Dr. Lee Newcomer, former executive at UnitedHealthcare | May 2019*Welcome to* [*The Precision Medicine Podcast*](https://www.interventioninsights.com/precisionmedicinepodcast)*, where experts come to discuss the problems oncologists, reference labs, and payers face as precision medicine grows, and consider solutions for advancing the quality of patient-centered cancer care.*

Jerome Madison: Welcome to the Precision Medicine Podcast. I’m Jerome Madison, host of the podcast and vice president of provider relations at Trapelo. And today, we have Dr. Lee Newcomer, former senior vice president of oncology and genetics at UnitedHealthcare. And we’re going to talk about the perspective of a former healthcare CEO and how they look at the precision medicine industry. It is very much a treat, Dr. Newcomer, to have you on the podcast. Thank you for coming on.

Dr. Newcomer: Well, thank you, Jerome, for inviting me.

Jerome Madison: You’ve had a really unique career. First of all, you’re a board-certified oncologist, and you made the transition to industry as senior vice president of a health plan. What brought about the opportunity to make the move into industry, and what has attracted you as and kept you in the oncology space?

Dr. Newcomer: Well, the move to industry actually began with a sabbatical program that we had in our clinical practice. Every ten years, we were allowed to take a couple of months off, and I had convinced my practice partners to give me enough time to go back and get a master’s in health administration, which was a combination of public health and a master’s in business administration. And during that experience, I started to realize that we could have huge impact on very large populations of people through policy making, through economic incentives. And I got interested in thinking about payers as a way to help change the medical industry in a positive way.

Jerome Madison: You know, we here at Trapelo lead the conversation about how we can pay for precision medicine, because we know we engage payers as well as the providers and clinical laboratories that do much of the testing that makes precision medicine possible. And you are the perfect guest to start with this whole conversation about why is healthcare so expensive? Why are the therapies so expensive?

Jerome Madison: I heard you speaking some time last year at Yale, and you talked about the FDA mandates for cancer therapy that in some way eliminates the competitive marketplace. And I think that’s a fascinating place to start for our listeners. If you recall, can you expound on that a little bit?

Dr. Newcomer: Well, sure. The Yale seminar was discussing why cancer therapies are so expensive. And there are actually two things going on that have a significant impact on cancer therapies. The first is the one that you mentioned, that they’re a protected class in most of the federal reimbursement programs and state insurance laws. Now, what we mean by that is that, by law, a payer is mandated to pay for any FDA-approved cancer therapy, regardless of value. If they have an FDA approval for even, say, a ten-day prolongation of disease-free survival, which is a pretty minimal impact, it must be paid for. That’s true for Medicare, Medicaid, and federal employees. It’s also true for commercial insurance in at least 42 states in the United States.

Well, with that guarantee, pricing could not be negotiated. If the manufacturer said, "This pill is $10,000 a pill." As long as they had their FDA approval, the payer had to pay. So as a result, when you look at price escalation for cancer therapies versus other classes of drugs, the price increases in cancer have gone up exponentially. 10x, sometimes 100x, compared to drugs that are used for diabetes or blood pressure control, or anything else because they don’t have that protected class.

My argument is, is that they ought to be able to compete. Now, the reason for that rule was that people were worried, and as cancer therapies got more expensive, payers wouldn’t pay for them. And I don’t believe that’s going to happen. But now, we have multiple drugs that do the same thing for the same cancers, and we can’t compete. We can’t take those several drugs to market and say we’re going to have a bidding process, and the low bidder would be the drug of choice for coverage because all of them have to be covered.

The second thing that’s going on is that more and more communities in the United States are dominated by either one or two health systems. In fact, 85% of our major markets in the U.S. The health systems are either a monopoly or a duopoly. That means when the health plan comes to negotiate with those health systems, they don’t have a lot of leverage because you can’t operate a health plan if you don’t have any hospitals. Those hospitals have acquired cancer centers, and one of their profit centers is the cancer center. It makes very high margins because they’re charging substantially more than the pharmaceutical manufacturer is charging for those drugs. Their markups, on average at UnitedHealthcare, were 156% above retail price.

Jerome Madison: Wow.

Dr. Newcomer: And when that negotiator said, "That’s unacceptable." The hospital negotiator then turned around and said, "Well, you don’t have access to our beds, then," because that’s part of the deal. So, unfortunately, with those monopolies and duopolies around, cancer costs have risen even more than the manufacturer price. And so it’s not at all uncommon to see a cancer patient getting a $30,000 or $40,000 chemotherapy bill every month if they’re in one of those institutions getting an expensive med.

Jerome Madison: I think that it’s really sobering information, and when we talk about real numbers, real therapies, you used an example of Crizotinib, which is an ALK inhibitor, the first generation that came out, and I’m not sure what the cost was. But when the subsequent therapies came out, instead of introducing competition in the market, the price actually went up. Those therapies that came behind had a higher price and, therefore, Crizotinib raised its price.

Dr. Newcomer: Yeah. Crizotinib was an excellent drug. It was a breakthrough medication for lung cancer patients who had an ALK mutation, and when it originally hit the market, it was priced at about $11,000 per month, but it prolonged life for these patients by a year and a half to two years, and these are patients who had no other alternative beforehand. Well, that’s great news, but then shortly thereafter, four other ALK inhibitors came to the marketplace, and by the time five years had passed, a couple of things happened. Number one, Crizotinib’s price had risen to $16,000 a month. I was pricing them here in the Minneapolis market, but the other four competitors were priced at $15,000, $14,000, $15,000 and $20,000 per month, even though they were follow-on drugs. Now, one of them, Brigatinib, has actually shown that it’s got a superior response rate than the original Brizotinib, so probably it deserves a better price, but my point is, with competition and multiple drugs, pricing should go down, not up, and in fact, in oncology, it’s going up.

Jerome Madison: So I’m going to skip to question four because I think it’s naturally follows into the conversation around price of diagnostics. So there’ve been many that have quoted data here on this podcast and certainly other places that has shown that diagnostics are about 3% of the healthcare spent but are responsible for 90% of the information needed to make treatment decisions with respect to oncology and targeted therapies. In some cases, that means $3,000, $5000 diagnostic test could guard access to a therapy that costs $150,000 to 200,000 plus a year, which could be a good thing to ensure we don’t waste time, money, or expose patients to unnecessary toxicity, yet many tests are still not reimbursed by payers. Why do you think there’s such a huge disparity in the value of diagnostic tests versus therapeutics?

Dr. Newcomer: While I’m in full agreement that if we can find biomarkers that identify exactly the right population for treatment, that’s a win for everybody. The patient avoids toxicity they didn’t need, if they weren’t going to respond. We don’t have to pay for a very expensive drug that isn’t going to work, and a biomarker would be key to that.

Dr. Newcomer: So I think the reason that people have been baulking is that good biomarkers have mixed up with bad biomarkers. And we can probably get into this discussion just a little bit later, but in the early innings of this industry, not all tests were created equal, and I think that’s caused the payer community to be a little skeptical about some of the results.

Dr. Newcomer: But to get back to your point, let’s just use a really simple one, the HER2 marker, which was actually not a genetic test but a simple immunofluorescent test. That has helped identify women who would get a life-saving treatment for breast cancer, and it has prevented other women from getting a treatment that wouldn’t have been helpful for them. It’s a classic example of how biomarkers could become very, very important. The ALK inhibitor that we just talked about is another good example.

So they have value. There’s no question about that, but, usually, what’s missing is the solid evidence that says this biomarker can be applied consistently, and the evidence is, almost has to be, as good as the evidence that the drug worked. I am not advocating for FDA approvals of every biomarker with that statement, but you do need good evidence to support that you can use that biomarker in clinical decisions.

Jerome Madison: Yes.

Lee Newcomer: Go ahead.

Jerome Madison: Well, and that kind of leads to, you just mentioned, the evidence has to be there. There have been quite a few laboratory-developed tests that’d come into the market over the last 10 plus, 15, 20 years, and I think you’re right. Clinicians, if you listen to the manufacturer’s reps that go out there, they’re all great, but the reality is they’re not. Besides having data, clinical validation, behind the utility of these tests in different biomarkers, what else can labs do to increase the value of these tests?

Dr. Newcomer: We probably ought to go back, though, to the actual evidence that a payer would want to see, and there are three of them. One is analytic validity. Does this test consistently measure what you’re saying it’s measuring? And CLIA does a nice job of making sure that’s the case. I don’t think laboratories find that level of evidence as a difficult thing to do.

The next thing they’re looking for is clinical validity. When I get a positive test, does that really mean that I have the disease you’re telling me it does? And clinical validity also is relatively easy to prove, but there’s certainly been some major gaps out there. The example that comes to mind for me was, we were once looking at one of the CYP2D enzymes as a marker for people who were able to process Tamoxifen therapy correctly. It turns out we were looking at the wrong mutation, but there was a pharmacy benefit management company that switched a significant number of patients off of tamoxifen to aromatase inhibitors, based on that test, before the clinical validity was really completed. And that just serves as a good warning for us, that we’ve got to make sure that if the test is positive, the patient has the problem.

Dr. Newcomer: And that gets us to the hardest one, which is clinical utility. Can I make a different decision for this patient, based on the result of that test? So, a lot of payers are finding that prognostic tests often fail that criteria. You might be able to tell me that I have a poor prognostic cancer, but if it doesn’t change the therapy, and if it doesn’t affect anything that I would do for that patient, it’s just informative. Then, it probably won’t be covered in the payer world at all.

Jerome Madison: For sure.

Dr. Newcomer: I think that’s been hard for some labs to understand, though, because they can clearly show that their test helps understand whether the tumor is more aggressive or less, but if the therapeutic world hasn’t caught up, it just doesn’t have value to be paid for, even though they clearly have a clinically analytic test that’s works. So that, I think, has been a source of huge frustration. Gathering that evidence for clinical utility is an expensive process, and I do think that that has raised the cost of developing laboratory tests, which payers probably haven’t adequately recognized.

Jerome Madison: Sure.

Dr. Newcomer: If they’re going to ask for that data, they have to understand that it will make the test more expensive in the long run because clinical trials, or gathering the evidence we’ve talked about is not an inexpensive enterprise.

Jerome Madison: Shifting to the different technologies in which we can find these different mutations or aberrations that can inform us which therapies a patient is likely to benefit from or not, next-gen sequencing, as we look at it, is really a fairly new technology. It’s only the last few years, but it’s certainly become kind of the go-to technology for sequencing and finding these aberrations. Do insurance companies have concerns paying for NGS testing, or does it matter the technology?

Dr. Newcomer: Well, there’s two issues going on there, and let’s deal with the first one, which is an economic issue. Early, as NGS testing came out, it was fairly expensive, thousands of dollars. And one of the things payers were wondering about was, "Okay, if I have a cancer, and I know that there are three genes I should be checking, but the physician or the lab’s requesting an entire exome or an entire genome or some 600 panel NGS test, the question was, were all of those unnecessary and clinically not relevant? So why should I pay for NGS testing, when I could just do the three specific mutations that are relevant to that cancer?" The economics are beginning to change. It’s almost, now, and in many cases, it already is, less expensive to do a whole exome with NGS than to do a battery of six or seven specific tests that we know are positive in that cancer. And I think you’ve seen the economics way, some of the clinical decision-making. CMS was persuaded, at least in the last year, that NGS sequencing could be done for a relatively affordable cost, compared to a discrete panel, and so you’ve seen them open up their coverage policies. So economics is changing a little bit about how the payers look at that.

Dr. Newcomer: The other issue, though, that still remains is, if I do a broad panel of, say, 600 genes, and I find a mutation for which there is a targetable drug, but that combination has never been used in the specific cancer I’m looking at, payers get a lot of pressure to say, “Well, that drug and that gene mutation worked in lung cancer. Yes, this is a sarcoma, but we want to try it because of lung cancer success.”

There’ve been a lot of trials that have shown that the mutation doesn’t and the drug don’t always work in a different cancer system. David Hyman at Memorial Sloan Kettering has done a beautiful job of illustrating that it doesn’t happen anywhere nearly as much as we’d hoped.

That kind of pressure to start approving one of those $100,000 therapies without any evidence but just the theory that it will work has caused people to be quite nervous about doing more testing than necessary. I think we are evolving to a point where people are realizing we’ve got to have the clinical evidence for the drug and the mutation combination in the cancer, and so some of that pressure is also beginning to go away. I think that’ll eventually open up coverage for more NGS tests.

Jerome Madison: I think that would be a real encouragement to these different labs out there to innovate, to create new tests, or to develop their data, but there’s kind of a catch 22 because there’s a lot of really great predictive lab products on the market. However, labs have to go to market before they have significant validation and get the market to use it, create demand, so then they can approach payers for payment. At least, historically, that’s kind of how it has been. But even then, they bill a list of stacked codes to at least recoup the cost and, hopefully, increase margins, but in many cases, it has resulted in low reimbursement. Do you think the cycle is an impediment to innovation?

Dr. Newcomer: Definitely, and a phrase that, that you used there, I think, is a complete red flag for the payer, and that is, they’re going to market before validation. And they aren’t going to market before validating their analytic validity. I think all of them have done that.

But they’re trying to develop the evidence case for clinical utility, while marketing the drug and trying to get payment for it, and for a payer world, that’s an anathema. You need the evidence first before the coverage begins.

That means that, unlike a decade ago, labs now need to find the capital resources to do enough testing in a clinical trial to prove clinical validity, and that’s something they didn’t have to do ten years ago, as you just pointed out.

Dr. Newcomer: Unfortunately, that method that you talked about, about trying some stacked codes together, to at least get payment, because the stacked codes were payable, but the entire task that led to those stacked codes was yet to be validated, got viewed as a highly negative approach by the payer industry. In fact, while I was at United, as we started doing analytics on what was happening, we found more than one company who had a test that was complex, and we could watch them billing various patterns of stacked codes and existing CPT codes until they found an ideal maximum reimbursement, same test, same company, and, often, as many as 50 or 60 different billing combinations for that over time as they were testing our systems to see what worked. That tainted the industry in the payers’ mind. That didn’t seem like a legitimate practice, and I think it left the industry believing that they had a real problem.

Dr. Newcomer: Simultaneously, as you looked at trends in laboratory medicine over the last three to five years, when genomics has become much more prevalent, the costs of laboratory testing are accelerating in triple digits, 110%, 105% trend increase every year, and that will always get their attention.

So between that trend increase and then going back and finding some of these practices about billing, the relationships between labs and payers deteriorated. As we’re beginning to move forward again here, though, and starting to understand, with better coding, that we can be more precise about how we bill and by asking for more evidence, I think that’s going to, that relationship will improve substantially.

I do want to come back, though, and give labs their due. There was no accurate way to bill for molecular testing in the early innings with the CPT codes. There just weren’t good codes, and so they were at equally at a loss about how to get payment for their tests, and I think we’ve got to develop a better CPT or test identification system in order to accurately pay for those tests.

Hence, you’ve seen, basically, genomic tests benefit managers move into the marketplace. And one of the services they’re providing is that they are getting discrete identifiers for each, every individual test. That means it can be paid accurately. It means also that we’ll know exactly what that test is for and what the evidence behind it is. That’s all good.

Jerome Madison: To this point of innovation and being able to afford the innovation, some feel the development of companion diagnostics should be governed by the pharmaceutical industry, since it is, ultimately, their drug which would be administered. What are your thoughts around pharma controlling development and reimbursement of these different lab tests versus laboratories controlling their own destiny?

Dr. Newcomer: It’s too big a conflict of interest for my preference. You’re asking a manufacturer to develop a test that will limit their marketplace and actually decrease their revenues, and what businessperson wouldn’t move pretty slow on that? So I don’t think it’s a reasonable ask to say pharma should be creating the biomarkers. They are certainly going to work very hard on creating biomarkers that will open new markets for them. That’s a perfectly rational incentive, but I’d like to see the labs continue to be the innovators for how could we narrow the populations down to people who are more likely to respond, to get the kind of precision that we need in oncology, because today, with almost every drug use, if we treat 100 patients, if we had a good drug, 30% to 40% of them will respond, and more than half of them won’t. And that’s wasted time, that’s wasted resources, for those patients. We’d like to be more precise.

Jerome Madison: Absolutely. So, Dr. Newcomer I did introduce you as the former SVP of Oncology and Genetics, but now, you’re retired, like all of us want to be at some point in our lives. How is retirement treating you?

Dr. Newcomer: It’s just absolutely wonderful. There’s nothing quite like being able to set your own agenda, and it’s really nice not to be working the 60 hours a week that probably everybody who listens to this podcast is working. So all of that is really nice, but what I’ve enjoyed about it is the projects I do get involved in are fascinating, and I think possibly very disruptive in a positive way for medicine. There’s a lot of bright people out there, trying to improve our medical care, and I think we have nothing but a bright future ahead of us, if we allow those technologies to merge and make us all better care providers.

Dr. Newcomer: Well, you’ve certainly been a visionary leader in the area of oncology and also on that payer side that has certainly laid a good path for those who come behind you. So we thank you for the work that you’ve done in the space and, most importantly, thank you for lending your expertise and your comments here on the Precision Medicine Podcast.

Dr. Newcomer: My pleasure, Jerome. Thank you.

Jerome Madison: You bet. We thank Dr. Lee Newcomer, as well as all of our listeners, for listening in on the podcast. Don’t forget you can download transcripts of this at precisionmedicinepodcast.com, and for those of you out there on social media, be sure to follow us on Twitter @PMPbyTrapelo, and also connect with us on LinkedIn on our company page, at Intervention Insights.

Jerome Madison: If you enjoyed this episode, we know that you know someone who would, so please tell them. They’ll thank you, and so will we.

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**About Our Guest: Dr. Lee Newcomer, M.D.**

Lee N. Newcomer, M.D. spends his time creating new approaches to make cancer care more effective and affordable. He utilizes expertise in medical oncology, health plan strategy and operations, health services research, finance and communications to create disruptive approaches for improved care of cancer patients.

The majority of his career was with UnitedHealth Group. He was their Chief Medical Officer from 1991 to 2001 where he built the company’s medical management programs. He focused his later work on the development of performance measures and incentives for the improvement of clinical care. He returned in 2006 to lead an initiative combining clinical, financial and program management experts to focus on cancer care. This team was the first to complete an episode payment program for cancer treatment and it created the first commercial cancer database combining clinical and claims data.

Prior to his work at UnitedHealth Group Dr. Newcomer practiced medical oncology for nine years in Minneapolis and Tulsa, Oklahoma. He served as the Medical Director for Cigna Healthcare, in Kansas City and he was a founding executive of Vivius, a consumer directed venture that allowed consumers to create their own personalized health plans.

He is a former Chairman of Park Nicollet Health Services (HealthPartners), an integrated system of physicians and hospitals based in Minnesota with national recognition for its leadership in quality, safety and cost effectiveness. He is a director at Cellworks and Intervention Insights.

Dr. Newcomer holds a B.A. degree from Nebraska Wesleyan University, a M.D. degree from the University Of Nebraska College Of Medicine and a Masters of Health Administration from the University of Wisconsin at Madison. His clinical training included an internal medicine residency at the University of Nebraska Medical Center and a medical oncology fellowship at the Yale University School of Medicine.

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