**EPISODE 16:**

**3 Trends That Can Change Cancer Care Forever: A 2-Part Podcast with Dr. Michael Kolodziej**

Dr. Michael Kolodziej | June 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, Vice-President of Trapelo and one of the hosts of The Precision Medicine Podcast. Today, we have Michael Kolodziej, Chief Innovation Officer at ADVI Health. Very much a pioneer in developing value-based reimbursement models for cancer care. Dr. Kolodziej, thank you for taking time to come on the podcast.

Kolodziej: Thanks for inviting me, Jerome.

Jerome Madison: For all of our listeners out there, I heard you speak at FLASCO, The Florida Association of Clinical Oncology, where you were the closing keynote speaker. Some of you may have heard him speak in different forms, but your talk was titled The Healthcare Landscape of 2025. Now, the subtitle was Three Trends That Will Change Cancer Care Forever. Now, Dr. Kolodziej, I got to admit, when you hear topics like that, some part of the brain kind of goes, "Oh, come on", right? At the end of your talk... It wasn't just me, it was other people who were like, "Yeah, what he said."

Jerome Madison: First of all, before we dive into those three trends, I'd love to give our listeners a little background on you. You've had a very successful career as a practicing medical oncologist, also, a business executive. Can you share kind of your path to ADVI Health? Also, tell us what the company does?

Kolodziej: Sure, I'd be happy to. I would say that like a lot of people, exactly how my career turned out wasn't what I thought it was going to be when I started. After finishing my training in hematology oncology, I decided to go into academic medicine, which I did for a while and I got tenure and decided that wasn't quite for me. I joined US Oncology back in 1997. The reason I joined US Oncology was because I didn't know anything about how the business of oncology actually worked. I think it's a sad statement that when we train fellows in hematology oncology, although the vast majority of them do wind up going into clinical practice, they have very little understanding of exactly how that sausage is made.

Kolodziej: I thought, "Well, shoot, I should go to a company that knows what they're doing", and that turned out to be one of the best decisions I ever made in my career. I moved to Upstate New York, my wife is from New York, so we moved to New York. My wife is also an oncologist. We both joined the practice here in Upstate New York. I had a very excellent mentor who had recruited me here and he decided that I had some leadership skills that perhaps could be useful in US Oncology. I began a clinical community oncology practice here in Albany and I di that for 15 years. During that period of time, I also became very involved in US Oncology, initially in the Research Committee area and then subsequently in the Pharmacy and Therapeutics Committee where I became Chairman and I got to become part of the Executive Leadership Team.

Kolodziej: Now, in the US Oncology network, the Pharmacy and Therapeutics Committee is really the most active clinical committee, and so I was there when we developed the Clinical Pathways Program at US Oncology, which is now quite well known. I was there when we developed our version of the Oncology Medical Home long before it was even a though for CMMI. I had a very, very great time at US Oncology, both because I loved the people I worked with, I loved the work I did, I loved patient care, and I learned a ton.

Kolodziej: In 2013, I decided to change directions a little bit. I had met many people over my career and was able to secure a position at Aetna, which at the time and is currently still the third-largest national health insurance company, the role that I was asked to fill at Aetna was to help develop oncology strategy. At Aetna I was very blessed to work with people who believed that there was value in developing an Oncology Medical Home program. We built on the learnings of John Sprandio and Barb McAneny, and we formed what continues to be the largest national payer program with community oncology practices.

Kolodziej: I also got to do pretty much everything an oncologist might want to do within a payer because anybody who's ever dealt with a payer knows that there's not that many oncologists that work there. Again, I had a really great opportunity to learn all kinds of stuff and I really worked with some excellent people. I was at Aetna for three and a half years and then I went to Flatiron Health. I had known folks at Flatiron literally from their conception and I always thought that there was a wonderful opportunity to use their framework to work on developing novel payment models. We looked at many of the practices that were working with Flatiron Health and helped them with the OCM.

Kolodziej: After about a year and a half, I was concerned that I wasn't making the kind of progress I wanted to make and was recruited by ADVI. ADVI is a Washington, D.C.-based healthcare consulting and strategy firm. We work with an extremely broad spectrum of clients from on the one extreme provider groups through many life science companies, including biopharma, medical devices, complex molecular diagnostics. I was able to apply many of the learnings that I had with my experience at US Oncology and then subsequently my experience at Aetna. Everybody is sort of confused about how payers make decisions and so that fundamental knowledge that I gained there is something that people value.

Kolodziej: On any one day of the week I might be working on a complex molecular diagnostic test in prostate cancer, and then on another day of the week be talking to a biopharma company about what's going to happen with the oncology care model and what commercial payers are doing. That's what I do now. It has been a very interesting job. I again have been very blessed to work with people that I really like. The CEO of the company and one of the partners, the Chief Medical Office, Marc Samuels and Louis Jacques respectively have been friends of mine for many, many years and we have a lot of fun, so that's what's important.

Jerome Madison: I can tell from just hearing your keynote at FLASCO that you do have this very comprehensive knowledge of just this particular sector that we're going to talk about and getting into your talk in the three trends. You talked about biosimilars, payer reform, and alternative payer models. Just dealing with the first one, being biosimilars, can you help us better understand I guess what biosimilars are? Then, cancer care, what malignancies are you seeing the most activity for a biosimilar drug development?

Kolodziej: Sure. The easiest way to think of a biosimilar is from the context of a generic drug. Now, I'm sure your listeners are going to go nuts when they hear me say that, but it really is the right framework to consider it. I don't think there's anybody in America, and certainly no provider in America, who doesn't use a generic drug every single day, and, in fact, generic drugs have to a great extent been a profound favorable influence on the cost of medical care in America. Why do I say that? Well, if you look back prior to 19484, there literally were almost no generic drugs, and in 1984 a very important piece of legislation, the Hatch-Waxman Act was passed.

Kolodziej: The Hatch-Waxman Act, which to this day is applauded as one of the most influential and important pieces of healthcare legislation ever passed, developed a pathway by which generic drugs were approved, by which reference products were protected. It introduced an avenue where America, and I do literally mean America, derived tremendous value after a period of market exclusivity based on the patent of various drugs that resulted in significant reduction in the cost of life-saving therapies. When I gave the talk, I jokingly said that I finished medical school in 1984, so I was there when this happened, right?

Kolodziej: It used to be patients were remarkably skeptical that generics were okay. In fact, people would come in all the time and ask you to write on their prescription, "Dispense as written", that is, they wanted the brand name drug, but generics have become such an important part of the fabric of medical care. I think if you talk to biopharma, they would readily admit that America has gotten a lot of value from that generic phase of the drug treatments life cycle. It's just the way it is.

Kolodziej: Now, it turns out that in the last 15 or so years, many of the most important advances in medical therapeutics are not simple small molecules. They're in fact complex molecules generally created in living cells through genetic engineering, and these complex molecules are kind of grouped under the heading of biologics. If you look, for example, in oncology and look at the cost of therapies in oncology, conventional chemotherapy versus biologic, it's absolutely crystal clear that in the last 10 or 15 years the trend that is driving increasing costs has been around development and implementation of biologic strategies.

Kolodziej: Now, I will tell you that the one exception to that is really just in the last couple of years and that's immuno-oncologic therapy, so IO therapy is a little bit different than what we're talking about here, but let's leave that aside for the moment. Now, there has been or there was never clearly the same sort of path towards a generic opportunity for biologic agents. Why? Generic molecules, generic medicines are exact copies, exact copies of the originator medicine, and biologics are far, far too complicated. In 2009, an important law was passed by Congress called the Biologics Price Competition and Innovation Act. That law developed the framework by which the FDA could evaluate and Medicare and other payers could pay for molecules that had the same biological activity as the reference biological product.

Kolodziej: Now, the hypothesis was that as those biologics came off patent, there would be the opportunity to develop lower cost alternatives. There was never, ever, ever the illusion that these lower cost alternatives would be easy to make and there really was never, contrary to what some people have written, there was never the illusion that the price decrease would be the same as we have seen with the generic drugs. Biosimilars are the result of a pathway from a single-source biological agent to a quote "generic equivalent."

Kolodziej: Now, we are in early days. Interestingly, Europe has been using biosimilars since 2006 because they basically developed this regulatory path before we did. If you look at the biosimilar spectrum in America today, in oncology specifically, the only biosimilars that are currently available are for supportive care agents, specific like growth factors. Erythropoietin, short- acting G-CSF, and long-acting G-CSF. Those are the only ones that are currently commercially available.

Kolodziej: We will see within the next year in the market biosimilars for Rituxan and for Herceptin, and those biosimilars will compete directly with the reference products. There are other biosimilars outside of oncology. There are biosimilars in the anti-inflammatory space. Biosimilars, for example, Humira and Remicade, and it would be fair to say that people have been a little bit disappointed, number one, in how rapidly these biosimilars products have come to market because FDA approval and market availability, those are not the same thing. These are very complex molecules. It takes a while to get up to commercial speed, so that's one thing that's bothered people.

Kolodziej: The other thing that's bothered people is that at market entry, the biosimilars have not been discounted as much as perhaps people had hoped. Now, I would suggest that people just hold on a minute, and the reason I say that is because I think if you look back at generic drugs there's an important lesson, and the lesson that the minute a generic drug hits the market, it is not much less expensive than the reference product. By the time you get the fourth competitor in the market, then you start to see significant price decreases, and we've actually seen this in oncology just very, very recently.

Kolodziej: The example in oncology, which I pointed out in the talk, is in the CML space. Gleevec was a miraculous drug. I don't think any oncologist who saw a patient with CML before Gleevec will ever forget what Gleevec did for that disease. It just changed it.

Jerome Madison: Absolutely.

Kolodziej: Gleevec was quite expensive. It didn't start out expensive, but over the years there were steady price increases and by the end it was pretty darn expensive. When Gleevec first went generic, everybody was expecting, "Oh goodness, we're going to see a drop in the price", and the drop was really slow and people started to freak. They really did. I was at Aetna at the time and believe me, we started to freak, but actually as it turns out, as more Gleevec generics have entered the market, imatinib generics, we have seen a substantial price decrease, in fact, to the tune of about a 75% discount.

Kolodziej: People who argue that we're not reaping the benefits, and just recently Peter Bach and Mark Trusheim wrote an article saying that we should just abandon this idea that the market is a solution for biological molecule price decreases. I think they're totally wrong. I think we have learned from experience that until you get significant competition in the generic market, and now subsequently I believe in the biosimilar market, we will ultimately see a decrease, and that is of course what Scott Gottlieb, former head of the FDA said all along. I agree with Scott.

Jerome Madison: I'll remind people, keep in mind that you were the former National Medical Director of Oncology Solutions at Aetna. We recently spoke to one of your good colleagues, Dr. Lee Newcomer, former executive at United Healthcare. He mentioned kind of the topic that there seems to be an issue with a lack of competition in the marketplace which encourages drug costs to increase instead of decrease. He talks about the FDA mandate that required all insurance companies to pay for all cancer drugs, and we see cases where drugs have come on the market and subsequent therapies that may have more potency and longer duration of response come to the market. Those initial drugs increased their price instead of decreased their price. Why does that not sound right? Why is that? What needs to be done to reverse that kind of a trend?

Kolodziej: Sure. I've heard Lee say this many times, obviously. He and I have dueled, I guess you would say, in the editorial press about what the correct solution is. I think there's a fair amount of truth in what he says and I think the heart of what he says is this. Because payers are required to pay for all drugs, there is no universe in which there's the ability to walk away, and if there's no ability to walk away, there's no ability to bargain. There's no leverage on the payer's part.

Kolodziej: Now, we've seen indications from the current administration that they are interested in using more market-based remedy to allow more aggressive negotiations around price. They have, for example, enabled Commercial Medicare Advantage payers to do step therapy, even across benefits. What's the solution? The solution is that I think any reasonable human being will look at a therapeutic class of drugs and come to the conclusion that there isn't much difference between many of the drugs. If that's the case, I don't think there's anything wrong with negotiating around costs as long as patients have access to the necessary sometimes life-saving therapies.

Kolodziej: What I say to providers, and I said it in the FLASCO talk, is, "Let me give you a choice. I'm going to let you prescribe a drug in a very effective class and I'm going to remove every single impediment that you have. I'm going to wave prior authorization. What's more, I'm going to let the patient have it without a copayment." Sounds great, right?

Jerome Madison: Absolutely.

Kolodziej: Here's the catch. There's six drugs in the class. You can only use them when I tell you. Will you take it or will you not take it? Now, I'm not in a position to enforce that, but in fact, I don't think that approach is so far-flung that we won't see it. I would say, much to the dismay of a lot of the people that I work with, that there's a lot of belief that the I/O class of drugs, particularly the PD-L1 class, is setting themselves up for that kind of approach and I think that's primarily because all of them are pursuing labeled indications that overlap with labeled indications of other drugs in the class.

Kolodziej: If you permit a payer to manage multiple drugs in a class in that fashion, then I believe that there is an opportunity actually to drive down costs.

Jerome Madison: You've been listening to Part One of our conversation with Dr. Michael Kolodziej on three trends that will change cancer care forever. Be sure to look out for Part Two where he shares powerful information about payer reform and alternative payer models.

Karan Cushman: You’ve been listening to Part One of our conversation with Dr. Michael Kolodziej from ADVI Health. On 3 trends that will chance cancer care forever. Be sure to look out for Part 2 where he shares powerful information about payer reform, and alternative payer models.

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**About Our Guest: Dr. Michael Kolodziej**
**Vice President and Chief Innovation Officer, ADVI Health**

Dr. Kolodziej attended college and medical school at Washington University in St. Louis, where he was Phi Beta Kappa and Alpha Omega Alpha. He completed internal medicine and hematology-oncology training at the University of Pennsylvania in Philadelphia, and, after completing training, joined the faculty at the University of Oklahoma School of Medicine where he was an associate professor.

1998, Dr. Kolodziej joined New York Oncology and was a partner in the practice until December 2012. He was an active member and executive on the of the U.S. Oncology Pharmacy and Therapeutics committee from 2002-2011 and chairman from 2004-2011. He served as Medical Director for Oncology Services for U.S. Oncology from 2007-2011. In this role, he helped direct the implementation of the USON clinical pathways initiative, the integration of the USON EMR into this program, and the development of the USON disease management and advanced care planning programs, now known as Innovent Oncology.

Dr. Kolodziej became National Medical Director of Oncology Solutions at Aetna in 2013. While there, he directed Aetna’s oncology delivery reform pilots and was the architect of the Aetna Oncology Medical Home program. He was also active in Aetna’s pharmacy policy, condition analysis, and genetics subcommittees.

In 2016, Dr. Kolodziej accepted a position as National Medical Director of Managed Care Strategy at Flatiron Health, where he applied the core tech and data capabilities of Flatiron to facilitate practice transformation and success in alternative payment models. He joined ADVI in 2017.

Dr. Kolodziej is a Fellow of the American College of Physicians, and he has published and spoken extensively on payment reform, personalized medicine, and practice care delivery transformation in oncology.