



Health Care Law Today

Health Care Law Today Podcast Episode 12: Personalized Medicine, the Health Care of the Future

In this episode, Foley Partners [Judy Waltz](#) and [Antoinette Konski](#) talk with [Edward Abrahams](#), the President of the Personalized Medicine Coalition, to discuss the issues facing personalized medicine and how the concepts underpinning the field may be applied to diagnose and treat COVID-19.

Please note that the interview copy below is not verbatim. We do our best to provide you with a summary of what is covered during the show. Thank you for your consideration, and enjoy the show!

Antoinette Konski

Personalized or precision medicine is the field of medicine that finds the best treatment for each patient at the right time. Physicians use diagnostic tests, medical history, circumstances, and values, as well as information from prior patient therapies, to prevent disease and develop targeted therapies that can expedite a patient's treatment and recovery. Recognizing in 2010 that precision medicine is the health care of the future, Foley & Lardner launched an industry task force to anticipate and serve client needs as they venture into this new frontier.

The Personalized Medicine Coalition, or PMC, is an advocacy and educational group that represents innovators, scientists, patients, providers, and payers to promote the understanding and adoption of personalized medicine concepts, services, and products. Dr. Edward Abrahams is the president of the PMC and has charted its growth from its original 18 founding members in 2004 to more than 200 members today.

I am pleased to have Ed as our guest to explore issues facing personalized medicine and how its concepts and emerging research may be applied to diagnose and treat COVID-19. Ed, thank you so much for being with us here today. Did I hit the mark on precision

medicine? Is there anything you would like to add by way of introduction to yourself or the PMC?

Edward Abrahams

I think you have defined personalized medicine very well indeed. Foley & Lardner, as you know, has been an outstanding partner with PMC in developing and promoting personalized medicine. Let me begin by noting, as you just did, that I have never met a patient who did not prefer getting the right medication the first time, rather than going through a process of trial and error because the right diagnosis could not be made in advance of selecting the right therapy.

The good news is that we have many more molecular diagnostics today to target the right treatments to the right patients at the right time, as is often said. But personalized medicine also promises lower costs for systems that incorporate the tests and treatments underpinning the field into their clinical work streams. This is very important. By becoming more efficient with targeted therapeutics and avoiding costly interventions that don't work, personalized medicine can help these systems save money, and, at the same time, provide better outcomes for individual patients.

In other words, and this is terribly important in today's context of constricted resources for health care, with personalized medicine, we can enjoy the benefits of innovation and reduce costs. But we have to be smart about how we develop these opportunities. At present, we have only anecdotal evidence that personalized medicine can deliver both clinical and economic benefits, which is why PMC is doing the research to demonstrate that even if individual therapies come with high price tags, as many in fact do, they can and will produce cost savings if we target them to only those patients who will benefit.

That, in brief, is the real promise of personalized medicine. We believe personalized medicine can provide tremendous value, not only to patients, but also to the systems and countries that in fact have the courage to implement it.

Antoinette Konski

Thank you so much for that explanation and background on personalized medicine and how it is being used today to treat and prevent disease. Ed, for me, one of the highlights of the year is the publication of PMC's annual report that summarizes the key advances the industry has made over the past year. When will the 2020 edition be released, and can you give us a preview of what to expect?

Edward Abrahams

Within the next eight weeks, the Personalized Medicine Coalition will publish the sixth edition of *The Personalized Medicine Report*. We used to call it *The Case for Personalized Medicine*, but we now believe that the case has been made.

The report is our effort to define the field by explaining personalized medicine's opportunity, documenting its status, and discussing the challenges it faces. It's a widely read report that is written for laymen, particularly policymakers at federal agencies and on Capitol Hill.

The sixth edition will, for example, show that in 2008, there were only five personalized medicines, which we define as therapeutics with biomarker strategies on their labels, on the market. Today, there are over 250, so you can see there's been enormous progress over these past 10 years or so.

While most of these products are in oncology, we have also seen progress in other indications as well, including cardiovascular illness, depression, and especially rare diseases. The report will also show that today there are 75,000 genetic testing products on the market, up from fewer than 66,000 in 2016. In other words, this is an exploding field.

Also new in this report are discussions of how advanced analytics, artificial intelligence, and machine learning are yielding new insights about how other biological and environmental factors, in addition to genetics, influence a patient's disease risk and response to various treatments, thus opening the door to preventive medicine, one of personalized medicine's most important if as yet unrealized promises.

The report documents how, by targeting effective treatments to those patients who benefit, personalized medicine can achieve key goals for patients and health systems. It can shift the emphasis in medicine from reaction to prevention with emerging technologies like liquid biopsies, which may be able to detect cancer before any symptoms occur. This is tremendously important and a great promise. It may reduce trial-and-error prescribing, which patients would absolutely love.

Personalized medicine can also cut the number of adverse drug reactions, which right now are the third or fourth largest cause of death in the United States. It can use cell-based or gene therapy to replace or circumvent molecular pathways associated with disease, thereby offering cures where none had existed before. It can reveal additional targeted uses for medicines and drug candidates. It will obviously increase patient adherence to treatment, as patients will be more likely to stay on medications that don't have dangerous side effects, for example.

Personalized medicine will also reduce high-risk invasive procedures, which it already has done in say, kidney transplants, for example. It will help move patient-physician engagement toward patient-centered care. And finally, as I mentioned, it could and should reduce the overall cost of health care.

The report makes the argument that outstanding challenges in regulation, reimbursement, and clinical adoption slow our efforts to capitalize on advances made possible by personalizing treatments. Overcoming these obstacles, as we write, will require a collaborative effort to keep up with the pace of progress in science and technology. And this is in fact the overall mission of the Personalized Medicine Coalition.

Judy Waltz

At the end of the day—and you mentioned this a bit in your comments—for personalized medicine to be a success and available to patients, it has to be adopted by the clinicians. How does that happen, and are there obstacles to that success?

Edward Abrahams

This is a key thrust of the Personalized Medicine Coalition because we are learning that clinical adoption is a much slower process than patients want and expect. For example, PMC will publish a study this week documenting that medically appropriate genomic testing is quite inconsistent across the United States.

That means, for example, that some patients in cancer are not getting available treatments they need. The study shows that coverage and reimbursement strategies are not the only barriers to personalized medicine, as you might expect. Other barriers include lack of awareness among providers and patients, not to mention socioeconomic factors, including distance and access issues.

In medicine, it doesn't necessarily follow that if you build it, they will come. There are many mediators along the way from discovery and development to adoption. We also know from another PMC-commissioned study of the value of genomic testing in cancer care, for example, that many patients who are eligible for effective targeted therapies, as determined by genomic sequencing of their tumor, still do not receive the best treatment option based on the results.

This practice gap can be attributed to the limitations in the availability and interpretation of test results, sample processing constraints, limited access to targeted therapies, and especially lagging awareness of the rapidly evolving field of personalized medicine among physicians and other providers.

We demonstrate in this study that if all patients who were eligible to receive a targeted treatment actually received it, the cost-effectiveness of genomic sequencing, which is sometimes alleged to be too high, would significantly improve. In short, along with public policy, we know that the downstream issues focused on clinical adoption are extremely important and must be addressed.

Judy Waltz

We are in a continuing debate with respect to drug pricing in the United States. How does that debate impact the future of personalized medicine and how would you address or make some recommendations as to how we price our drugs?

Edward Abrahams

That's a very important question because as you know, the drug pricing debate has gripped public attention. But we are not considering all ramifications. The debate has particular implications for the development of personalized medicines, which tend to be more expensive but may together have a positive impact on the health care system and on overall costs.

We have to ensure that innovative products remain accessible, including to those who cannot afford them. But we also have to be careful not to remove the incentives to discover and develop those products in the first place, which I am afraid that price controls—no matter how they are implemented—would do. That is to say, they would stifle innovation. Drug development is a risky business. There are no guarantees. If we move or decrease the financial incentive to find new cures to unmet medical needs, it follows that we're going to see fewer interventions.

Late last month, President Trump issued an executive order to tie the prices paid for physician-administered drugs, many of which are personalized medicines, to those that are paid in other countries. That may be politically popular because those other countries pay less. But the policy, if implemented, will have disastrous unintended consequences for the development of say, new cell-based therapies, gene therapies, and targeted medicines that are only now reshaping health care in ways no one thought possible ten years ago.

This is so because there are incentives in place to encourage the development of groundbreaking therapies. It's important to understand that when a pharmaceutical company invests in, say, finding a one-shot cure for spinal muscular atrophy—a rare and debilitating disorder that affects fewer than 25,000 people in the United States—it does so without any guarantee of success, and it does so also with very high up-front costs that must be recovered. If the company that develops the cure cannot get a return on its investment, it's unlikely to take these big risks upon which patients depend. Long story

short, patients will suffer and the costs of providing care—not cures—for those patients will remain higher than they could be.

Antoinette Konski

I'd like your opinion on a topic of current urgent and global concern. Today, we are challenged medically and economically with the COVID-19 pandemic. How have the principles of personalized medicine been applied to diagnosing and treating COVID-19?

Edward Abrahams

I actually believe that the principles of personalized medicine that emphasize stratified responses, even when it comes to public health, have significant implications for diagnosing and treating COVID-19. Those principles, I believe, should inform future interventions to stem this terrible pandemic that has already killed over 170,000 people in the United States alone.

I don't think these principles are being adequately considered as part of the debate. PMC looks forward to introducing those principles, because they're so very important if we're going to effectively address this pandemic.

First, we have been very slow to develop and deploy real-time diagnostics—the backbone of personalized medicine. These diagnostics give us the tools to determine who is at risk, so we don't have to put in place one-size-fits-all public health responses, including closing down whole economies, when that might not be necessary if we knew who had the disease or who was likely to get the disease.

To date, we have not been able to target long-term prevention and treatment plans to the most at-risk populations, which would be enormously helpful in reopening economies, which we would obviously like to do sooner than later.

Second, and equally important, we know that the coronavirus expresses itself differently among different populations. For example, older men, racial and ethnic minorities, and those with particular underlying conditions seem to be more vulnerable to disease. It behooves us, therefore, to understand the molecular and environmental reasons for this differentiated response, and to develop and deploy therapies and vaccines that are targeted to those who are in need.

Today, we are looking for one-size-fits-all solutions because there's an urgency to find one. But eventually, scientists in my opinion are going to recognize that, because not everyone responds the same, different medicines are going to have to be developed to treat COVID-19 and other viruses.

We've already seen this in AIDS, and so I don't think the coronavirus is going to be different. We have to be really smart about how we address this pandemic. By the way, on September 3rd, PMC is organizing a virtual seminar, titled *COVID-19 and Personalized Medicine: Current Status and Lessons Learned*. It is free, and if you want to register, you can do so on our [website](#).

Antoinette Konski

Ed, thank you so much for being with us today, and as we wrap up, I'd like to invite you to make any closing remarks or comments on the topics we covered today.

Edward Abrahams

I'd really like to thank you both for your loyal support to the Personalized Medicine Coalition, and for giving me the opportunity to discuss these very important issues with your audience. I hope people will pay attention to personalized medicine. We believe it represents the future, and we also believe that if we invest in it, if we come together collaboratively as a community, we can have a health care system that we deserve based upon the developments in science and technology, which have never been more promising. Again, thank you for your attention, and I look forward to working with you and everybody on this podcast to move this field forward. It's not going to happen by itself.