Support for this program is provided by CSL Behring, Takeda, and Grifols. Doctor Marcus Shaker is a professor of pediatrics in medicine at Dartmouth's Geisel School of Medicine. On this episode of the Immune Deficiency Foundation podcast, he joined staff members Angie Kotarsky, community resource navigator, and Stephanie Steele, director of payer relations and policy to discuss prevalent issues surrounding insurance coverage for primary immunodeficiency patients. To donate, volunteer, or learn more about PI and the immune deficiency foundation. Visit primary immune dot org.

Dr. Shaker: Well, hey, so so Angie, it's good to connect with you again. We we met at the American Academy of Allergy, Asthma, an immunology meeting this February. And I remember we were kind of talking about some issues that are challenging, you know, our patients and our communities. It's great to great to reconnect with you again. How have you been?

Angie Kotarski: Doing really well. Thank you so much. Yeah. We're I'm still still here at IDF running the Ask IDF box as we call it, and answering lots of questions from our community. I'm if you remember, I'm a community resource navigator here.
And so, yeah, just answering lots of questions. And and with Stephanie, who's on with us too, and she's been really a great resource as well for our community.

Dr. Shaker: It's Stephanie, I don't know if we've met. I I my name, Mark Shaker, I'm a a professor of pediatrics in medicine at Dartmouth, and You know, I've I've been really, you know, touched by some of the experiences my patients have and I, you know, shared some of their frustrations. And so I think it's, you know, and Angie and I have chatted about some of these issues before, Do you also work on behalf of patients over at the immune deficiency foundation?

Stephanie Steele: I do. So I'm the director of payer relations and policy, and so I work with our constituents directly. I work with the different payers. Regarding policy issues that come up and they are keeping us on our toes this year, so to speak.

Dr. Shaker: Oh my goodness. I mean, it's such important work that you all do, but it must be kind of kind of frustrating at the same time. I mean, like, you know, kind of, Angie, you're on the front end, kind of hearing kind of the concerns of our patients and Stephanie, you're trying to kind of really institute change. I'd love to hear kind of some of the experiences you've been having in some of the struggles.

Angie Kotarski: Yeah. So Stephanie and I have worked together on a lot of these issues since, you know, I might be the first line, but then Obviously, I have to bring her in because she's the expert and she has all the connections as well. And one of the issues that I hear that I'm curious, doctor Shaker, if you what you hear from your patients is the the issues of step therapy P. So, you know, for example, we have a lot of community members that call in that have been on a certain product for a number of years, but their plan maybe has changed or maybe they have a new insurance plan that is requiring them to go back and try by other brands first before they can be on the brand that they that's best for them, for whatever that reason is. So I'm just curious if you had have you had that issue on what Texas tests have you had in getting patients on the therapy that you think is best for them and what they really want to be on that's best for their situation and their health.

Dr. Shaker: : I think this is so frustrating for patients. These step therapy the step therapy approaches. And I think if I was going to say, what's the root cause of the problem with step therapy? I think it's a failure of payers to appreciate evidence informed guideline based practice. You know, I mean, payers are still, you know, back in the nineteen fifties and a very paternalistic model, you know, where father knows best.
And, you know, we're gonna make sure that, you know, you're getting the care that you you you should get and that all care is right for everyone in one size fits all, but that's not the way medicine is practiced anymore. I mean, so I guess anything we're talking about today or just my opinions. But But I've been fortunate enough to work with some of the guideline groups within allergy and immunology. And allergy immunologists and really clinicians and physicians around the world are now using a method of guideline development called grade. And what Gray does is it separates evidence certainty and really very critically evaluates evidence certainty, you know, as very low, low, medium, or high.
But then it balances out recommendations in terms of feasibility and equity and cost effectiveness to determine whether recommendations are strong or conditional. And so I was just having a conversation today with one of our fellows in clinic. And and I said, strong conditional recommendation is really, you know, one of my North Stars. Right? So from a population health standpoint, you know, a strong recommendation can be a policy metric. It is it is generally a recommendation that everyone's going to want to follow. Right? But the reality is many recommendations we have in medicine are conditional. And a conditional recommendation is a navigational signal for shared decision making. And so shared decision making is a really critical way that we practice medicine in twenty twenty five.
It is where the clinician serves as the expert in the content and the medicine. But that patient and their family serve as the expert in their own preferences and values. Okay? And so Mhmm. The the the course that's taken is really dependent on that relationship.
And the patient has tremendous agency and what has happens. And so we usually say, well, strong recommendations have have clear policy implications, but so the conditional recommendations. You know, conditional recommendations will require flexibility so that shared decision making can occur. And By failing to appreciate the role of conditional recommendations, what insurance companies do is they seem to assume that all

recommendations are strong and there's only one way to go and you've got to go through step A, B and C. And I think the initial way that this was sort of sold was that we're just advocating for appropriate care in case your clinician doesn't understand what appropriate care is, which which in and of itself is kind of a mind blowing sort of thing.

Right? That you can't have a conversation with a clinician you trust and come to the right decision. You've got to have, you know, an insurer now double check everything that your clinician is telling you, which was never the purpose of third party payment. Right? But more broadly, what happens is that you get these situations where a patient's trying to get access to a needed medication and, you know, they hear from a payer prove that you need it.

Right? And to the patient, what they might hear is you haven't earned it. Right? And the clinician realizes that real world effectiveness is very different than clinical efficacy. And these have these have tremendous consequences.

So Scott Bickel and colleagues did a study. Goodness, a few years ago, and they looked at this was in Jay Journal of Pediatrics in twenty twenty one. And so they looked at the impact of payer initiated switching of inhaled corticosteroids on lung function. You know, they they took fifty eight fifty eight kids who were doing great on their asthma inhaler and the insurance made them switch, and they found a fairly significant proportion who had impaired lung function based on that switch. And, you know, we all know that probably a lot of those kids may not find themselves back in clinic to even get the appropriate therapy. You know, there was another another study by Gregor Dutyak, and they looked at the time lapse to get your biologic from an insurance, you know, from an insurance standpoint and all the delays that are introduced. And they found, you know, it took like a month and a half for people to get their biologic because of all these delays. And in the process of waiting, a lot of these patients had pretty severe asthma. They ended up having asthma exacerbations and the mean cumulative dose of prednisone that they had to take because they were waiting for their biologic because of the insurance hassles was nearly five hundred milligrams. Unacceptable.

Unacceptable. Unacceptable. And it's it doesn't have to be this way. You know, there was another study in in Journal of Allergy and Clinic immunology and practice in twenty twenty three by Porgera Berg, and they looked at the global variability of at least administrative approval. And it's not all delayed like this.

You know, we know that that, you know, when an insurer says, hey, you've got to take this medicine and you've got to prove that you've been taking this medicine for a few months before we'll allow you to have a biologic. We know that adherence is not a monolith. Right? And we know that Andrea Aptar studied this back in twenty thirteen. She showed that rates of medication adherence corresponded to health literacy.

Right? So if you're – if now you're using adherence is your metric in order for someone to get

a necessary medication. You're not discriminating on adherence. You're you're just discriminating, you know. You're discriminating.
So, you know, it's it's I mean, and so I'm very happy, Stephanie and Angie, that you're out there, fighting on behalf of our patients, because as much as we can talk about it, a lot ultimately a lot of these are going to be policy solutions. Let me tell you a story. Let me tell you a hypothetical story of a patient named Jeremy. Okay? So imagine, you know, imagine we're seeing this patient together and we're counseling the family of sixteen year old Jeremy.
Right? He's He's an adolescent with severe persistent asthma. And I'll tell you that he's had three asthma admissions. He said two ICU stays and he's been intubated with the breathing tube once. Okay?
He's got multiple environmental food allergies, and he's a sweet, sweet kid. He just doesn't take his medication. Right? And so I go ahead and and and I write him a biologic, which is perfect friend. I write him omelezumab, right?
His insurer refuses to cover it until he will demonstrate adherence to his ICS lab budesonide formoterol inhaler. You see the cyclical argument here.

Stephanie Steele: Right? Yeah.

Angie Kotarski: Precisely.

Dr. Shaker: know, and how is that saving anyone any money? Right? I mean, you know, it's it's Well, and then the thing that really gives you pause. Okay? So Victor Roy, two months ago in the JAMA Network, February issue.
He looked at shareholder payouts from large publicly traded healthcare companies. You know, they totaled over two trillion dollars. Over two trillion dollars. And at the same time, at the same time in the past twenty years, in the past twenty years, the US taxpayer provided at least some funding to the three fifty six new drugs that are approved. In fact, taxpayer dollars were behind three fifty four of those three fifty six new drug approvals to a price tag of one hundred and eighty seven billion dollars So, I mean, the issues are large, but ultimately, they get to the fact that if we as a society, are paying for the development of pharmaceuticals in R and D, not all of it, but a big chunk to the tune of hundreds of billions of dollars.
Why is it that we're not at the table when those drug prices are being set? Okay, almost as an for instance, almost as an outmatched study, almost as an out approved for peanut allergy, right? The outmatched study funded by federal dollars, a drug that's been on the market for over twenty years has a wholesale acquisition cost of over thirty thousand dollars a year.

Stephanie Steele: Oh my goodness.

Dr. Shaker: Why? Why is it? Why not? Why not drop the cost tenfold and sell it to a hundred times as many people? Right.
I mean, there are solutions. There are solutions. It's just it's a matter of having the will to to implement those.

Stephanie Steele: Absolutely.

Angie Kotarski: That's a really fascinating and great idea. That's like, for a solution. That's a really great idea. I know Stephanie recently had a community member with a situation where she had to go off of therapies. Stephanie, you wanna talk about what happened with this young young lady.

Stephanie Steele: Oh, yes. So we had an individual that had been doing well on her twenty percent product for quite some time. There was a policy change and she was forced to change products. She ended up needing Botox for her migraines, which cost her an unreal amount of money and occipital nerve blocks because of these migraines. And it's simply because the insurance company wouldn't grandfather, you know, the product that she was on in their formulary.
They offered one twenty percent product, one twenty percent IG product and one IVIG product. And there were only two on the policy, and that was it. And this individual has already had already failed that twenty percent product that they were forced to try again, and that was the outcome. And I I the position is still fighting with the inter with the payer. So

Angie Kotarski: Yeah. And it's fascinating to me that they don't see that in the long run, it cost them more money. Right?

Dr. Shaker: Well, and and and and so it's so so, you know, so the question, you know, I guess, Angie, is is what's the cost of of of human suffering? Right? What's the cost of human life? And so, you know, the great comedian, Jack Benny, you know, had a had a had a comedy sketch back in in nineteen forty eight. It was and it it was on his radio show.
And I don't know. You'll remember Jack Benny. So Jack Benny was a was a comedian famous for his timing. He was also famous for being a penny pincher. And so in the routine, This would be Robert comes up to Jack Meny and says, hey, bud, your money or your life. And Jack Meny doesn't say anything. And he says, hey, bud, did you hear me? I said your money or your life. And Jack Benny replies, I'm thinking it over. So so to the audience kinda laughter and so but but it it is I think it still resonates with people now because it it is this idea of you know, a patient should never be forced to answer that question.
You know? Right. Is it your money or your life? You know, we should we should have a system where people can get the basic care they need. And, you know, part of the problem

is that our medications cost too much.

Right? So why is it that IVIG is sixty thousand dollars a year in the U. S. But twenty thousand dollars a year in Canada. Right?

I mean, where is that? You know, what what what? I mean, I mean, how is that something that that that that that we promote and that and that we built a we built a society on it. So a lot of these sort of sort of tricks that people play. Right?

And I mean, we could talk about a number of tricks that people play. And I'm sure there'll be new tricks next year. Right? But they're all an approach try to get a handle of the fact that these drugs are way too expensive. And so I come back to the question, if we're the ones paying for R and D or at least some component of that, why isn't there a timeline of these of the drug costs?

Right? So I understand you know, a drug has to has to recoup its own R and D. A drug has to recoup the R and D or all the other drugs that didn't make it, but it doesn't have to do that forever. Right? And so Yeah.

Why does omelizumab have to keep charging the same wholesale acquisition cost for two decades? And at what point is that going to start to come down? And what are the downstream effects of this that we don't even realize? Right? So remodeling an asthma. Right? We learned years ago that inhaled steroids don't affect the remodeling as much as we wish they would. Right? And that might be because of ventilation, perfusion mismatch, because the areas that are more inflamed and plugged are not getting the inhaled medicine, right? But it might very well be that if you gave a biologic and you could now reach areas of inflammation that were previously unreachable, you could potentially prevent remodeling in the airway.

But Yeah. Still insurance. You know, insurance companies, you know, I had a patient today, effectively managed on a on on a biologic, but the insurance company begins to push back despite that that the patient being effectively managed because they're not they don't see the claims data for less effective medications that they require the patient to be taking alongside this other medication. So, the insurers are requiring patients to take risks of medications. They may not even need if they're on a biologic.

And it gets back to this question of understanding the role of shared decision making in medicine and being honest, right? So I think if payers are really honest about why they're holding people to this step therapy, it would become pretty apparent pretty quickly. It's not for the benefit of the patient. Right? It's for quality control.

It's to deny it's to deny people medications. And to deny people medications in an inequitable fashion. Right? Mean, I don't want to put too sharp a point on it, but there are multiple determinants of pharmaco equity. I mean, that includes risk, their patient factors, their employment status, their language and literacy, the health system factors, the provider geographic access, the health policy factors with people who may not even have insurance coverage, and then, of course, social policy factors like transportation. Realizing that millions of patients can't even access care because they don't have transportation.

Angie Kotarski: : Right, right, there's - in your - like you said, we, as in our organization, providers, patients, are coming at it from a completely different lens than insurers are, and that's and that's why those that I mentioned first, the group of us that I mentioned first, were coming at it from life as valuable perspective or as insurance seems to be coming from it coming to it from a financial perspective only. And when you're just not even looking at it the same way, it's very frustrating for everyone. But your comment about the geographic issues, kind of it makes me wonder, have you ever had any issues with any of your patients, with site of care with insurance requiring, you know, an infusion suite that the patient being infused in an infusion suite versus in their home.

Stephanie Steele: And just to jump in here real quick, I mean, we've seen, what I've seen recently is individuals be approved for subcu therapy, but be mandated to an infusion suite, where, of course, there's only one subcu drug that can add an infusion suite. So, I mean, the payers are becoming more and more tricky And, you know, sometimes we have individuals that live hours away from an infusion suite. So, yeah, that's something that we were curious about is how often you see sight of care as an issue?

Dr. Shaker: : Well, we have seen this. And, you know, it's incredibly frustrating. And health healthcare systems are not immune, right, which I think is one of the most frustrating things. So there's this issue where you know you can you can prescribe a medication and it might be insured by the it might be approved by the insurance, but they'll require it to be filled at a specific pharmacy, you know, hundreds of miles away, right, in a different state. Mhmm.
And then the idea is that pharmacy will then send the drug to the hospital where it's going to be infused. And that's called white bagging. But the hospital will say, okay, well, we'll provide it, but we won't accept the white bag. If we're going to do it, we have to fill it here because there's a financial incentive to do that. And so the patient is now completely stuck in the middle because Mhmm.
They can't get the their clinicians can't provide them the care they need unless they take a huge financial risk and then you get into issues with having it run through a pharmacy benefit versus a medical benefit, it gets incredibly confusing. It's not always smoothly done. Patients can get stuck with bills of tens of thousands of dollars. And and and and it delays care. Right?
And it's an equitable. Yeah. And and so I think it's I think it's I think it's I think it's tragic. And look, I mean, you know, at the end of the day, you know, no matter, you know, where people

are on the political spectrum. Okay?
Everybody agrees that they are not a commodity. Right? Nobody wants to be a commodity. Patients are not commodities. And so, I don't You know, I I I I I puzzle over over why we haven't had the political will in this country to do something about this.
Because, look, you know, we're all gonna be patient someday. Right? And if we're not patient yet, we have family members and loved ones who are. So so those of us in this country who hold levers of power to make change should do so because, you know, if not if if not you, then whom. If not now, then when?
And, you know, every system is designed to get the results that it gets. And we are getting exactly what we've designed our systems to do for us. And it's a mess.

Stephanie Steele: It is a mess. Yeah. Speaking of messes is our what are what's been the most challenging for you? Like, most challenging payer slash insurance situation that we have not touched on yet?

Dr. Shaker: Well, you know, I think that there are I I I think that the the challenging situations relate to these these core issues. Right? These core issues of, you know, you know, what did they say to, you know, the bank robber, Willie Sutton, in the eighteen nineties? Hey, Willie. Why do you rob banks?
That's where the money is. Right? So if we wanna understand, you know, why we struggle way we struggle. We've got to follow the dollars, right? And we've got to hold everyone in the healthcare enterprise accountable.
Physicians take an oath. When they graduate medical school. Right? We take an oath to advocate on the behalf of our patients. Right?
So somehow, there are players all throughout the healthcare system now that don't take that oath. Right? And I would say that everybody involved in the healthcare system, clinicians, payers, everybody. You know, insurers, drug developers should take that oath. Right?
Because we shouldn't be in medicine to pull money out of the system. We should be in medicine to provide care for the patients. And I believe that the majority of people who are in this enterprise are doing it on behalf of the patients. I don't mean to be too cynical here. Right?
I know I'm pointing out some flaws that we have, but I do think that everybody at the end of the day wants to do the best for the people who are suffering. Right? I just think that we get sidetracked, you know, and and and we lose our focus. Right? At least I like to think that and I've talked with my friends who are who are at all these levels and people are committed to patients and to drug development and to equity.
And so I think if we can kind of look at this more clear eye and and but but everybody realizes the system is broken. So I think it's a matter of coming together and trying to fix it

in, you know, the way we've tried to start up, we've tried to start by just making sure that insurers are aware of guideline based care. Right? Because because payers don't need to fool themselves that by treating every recommendation is strong and limiting flexibility and access to medications that they're doing that, you know, to provide better care people because that's just not the case. And so if we can begin through our national organizations to reach out to payers and say, look, these are the guidelines.
And, you know, your role is to provide guideline supported care. Right? So you need to be doing that. And then to do that, you need to know what they are, you know. And so these issues Right.
And the other aspect that I that I know are are partners you know, our third party payer partners really are it feels strongly about its equity. Right? And so I think as they realize that these systems of care that they set up challenge equity, basic equity, and discriminate against vulnerable populations. I think they're more likely to think twice about that. So I think those are very, very powerful arguments.
And, Stephanie, I don't know what your experience has been taking these arguments to the source. I'd love to hear kind of kind of what's going on on your side and and and, you know, you know, we we can't get to the solution until we describe the problem. But I think we've described the problem pretty well. So now we need to kind of begin to focus on what are the solutions.

Stephanie Steele: Absolutely. And, you know, we've reached out to several payers. The typical response seems to be, if you have a particular situation, let us know. But there are several people that have that particular situation that are not going to reach out. So it needs to be on a broader level where we have where we get the fix.
You know, we don't we we appreciate you fixing, you know, a situation for a particular patient or constituent, but it there are so many more that aren't speaking out. So that's where we're trying to make a difference is across the board, not just we're gonna help this person or this person or this person. It needs to be a policy change.

Dr. Shaker: Right. Because because that gets that gets to equity. Right? Because not everybody's gonna send that to you, you know. And so it almost seems like there needs to be, you know, a vehicle to have those discussions.
Right? We're okay. We're gonna meet quarterly with these decision makers, these people who hold levers of power. And we're going to talk about what the issues are. We're going to talk about we have more patients.
And I would hope that at least the people who are in those positions. Right? That are entrusted in those positions, would be able to make the time three or four three or four for three or four hours a year to have those conversations. Because otherwise, they they're

completely out of touch. Right?
And so I think that that's in everybody's benefit.

Stephanie Steele: Yeah. I would be It's more challenging than you would than you would think to arrange these meetings. I will say that. It it's more challenging

Angie Kotarski: to even get any response. At all is a challenge.

Stephanie Steele: Yeah. To get someone at the table. It's it's hard. They it there's just no interest and it's not because it's not coming from our end.

Dr. Shaker: Yeah. Yeah. No. I mean, I I it's challenging and and and You know, maybe maybe folks will listen to the podcast and rethink their availability for these meetings.

Stephanie Steele: I certainly hope so.

Angie Kotarski: That would be that would be amazing. That would be the whole goal of this podcast. Right? Yeah. That's what makes sense.
Do you find this same pushback when you do peer to peers?

Dr. Shaker: Well, I mean, I mean, peer to peer is is is challenging. Right? Because it depends on who you're getting as a peer. And Mhmm. And I've seen tremendous variability in that.
And I've had situations where a payer won't even allow or peer to peer. They'll just refuse it.

Angie Kotarski: Yeah. They fight at replacement.

Dr. Shaker: Yeah. Yeah. And and again, because it's all I mean, I I I think it's a matter of getting down to that question of we all need to take an oath. We all need to take an oath. Right?
And people need to need to come to work in these positions with the idea of of course, you know, being being good financial stewards for the for for for where they are. But but more importantly, making sure that they're providing care to the patients who need the care, not their customers, to the patients who need the care. Right. But, you know, I'm an optimist, Stephanie, Andy. And I'm optimistic that by working together, we can make impactful change for the better.
My great great grandfather was was Atticus, hey good. And he he was a he was an he was an innovator and he was a leader and he had a he had a saying and and one of the things actually on his tombstone would stand by the good and make it better when you can. Right? And so we don't have to solve all the problems. But if we can kind of if we can make ripples, you know, for the better, then then then we can be proud of of of of the work that we do.
And so I think these these sort of conversations coming together, you know, checking in,

you know, seeing where we are on this, you know, seeing if we're all, having similar experiences help us realize, you know, where we need to go. But but but, you know, there's only so much that can be done with advocacy. A lot can be done with advocacy. But but you know, I think policy solutions are probably what we need, you know.

Stephanie Steele: Absolutely. Yes. And I can't say, in the immune deficiency foundation, we are taking one hundred and fifty constituents to Capitol Hill on May first to speak with legislators on a non partisan level about some different core values that IDF has that are impacting community. So we're hoping that will make a difference as well.

Dr. Shaker: Well, I know my patience and I know my colleagues and I know myself. We're also grateful for the work that IDF is doing. You know, it it it really it it makes a difference for for all of us to know we're not alone. And that and that we're all working to make things a little bit better. So has there been great chatting with you and reconnecting?

Angie Kotarski: Yeah. Yeah. You too.

Stephanie Steele: Thank you so much for your time. We appreciate it very much.

Dr. Shaker: Yeah. You you guys have a great day, and thanks again for all you do.