Advocacy

George J. Hruza, MD, MBA, FAAD, interviewed by M. Laurin Council, MD, FAAD

M. LAURIN COUNCIL, MD, FAAD: Hello and welcome to *Dialogues in Dermatology*. I am Dr. Laurin Council, your Editor-in-Chief. And I have the distinct pleasure of speaking today with Dr. George Hruza. As you know, Dr. Hruza is the current President of the American Academy of Dermatology. He's also an adjunct professor at St. Louis University. And I am really excited to be speaking with him today on the issue of advocacy. Welcome, Dr. Hruza.

GEORGE J. HRUZA, MD, MBA, FAAD: Well, thank you. Glad to be here.

LAURIN COUNCIL, MD, FAAD: Well, can you first update for our listeners what some of the hot topics are, as far as advocacy in dermatology today?

GEORGE J. HRUZA, MD, MBA, FAAD: Well, there are a number of issues. The one that we're dealing with quite intensely right now is prior authorization. It's a headache. It's really a pain in the neck for just about all of our members, because of the amount of time they spend on it. Dr. Lebwohl has three full-time staff and at Mount Sinai, just dealing with prior authorization.

And we've had some successes. We've had the prior authorization reform for Medicare Part B, where it's been streamlined to make it a little easier and improved the appeals process. This year, we are pushing for prior authorization reform for Medicare Advantage plans, where we don't only get prior authorization reform for drugs, but in fact a lot of insurance companies are now asking us to get prior authorization for procedures.

And even for procedures that you can't anticipate that you're going to have the procedure.

M. LAURIN COUNCIL, MD, FAAD: Right.

GEORGE J. HRUZA, MD, MBA, FAAD: So we are trying to fix that. And this legislation would do that for Medicare Part B – I'm sorry, for Medicare Advantage plans. And then we've actually had some success in states. In Missouri, where I live, last year we got a bill where, when it was presented to the legislature, the insurance company lobbyists said it's the worst bill they ever saw. So we were very pleased that we were able to get that passed.

M. LAURIN COUNCIL, MD, FAAD: Wow, good job. Another recent advocacy success is with the issue of in-office compounding. So this is something that affects dermatologists all the time, whether it's mixing up a steroid that we're going to inject, sometimes we dilute those down. Botulinum toxin for cosmetic use is another example. But probably the most common dilution that we use in surgery is to buffer our lidocaine with sodium bicarb. What is happening with regards to in-office compounding?

GEORGE J. HRUZA, MD, MBA, FAAD: So in-office compounding, or we like to call it in-office preparation of sterile medications, has been a hot thing for about two years now. We've been dealing with it and made some progress. So we've been able to get the FDA to basically back off, so say if you do in-office things such as buffering lidocaine, even though we considered it compounding, we are not actually going to go into your offices to check on that. It's part of their draft guidance on insanitary conditions.

So the FDA has kind of backed off a little bit. However, the United States Pharmacopeia, or USP, published their revisions to Chapter 797 which deals with compounding and which is, once approved, ends up being adopted by states. Originally, they said if you buffer lidocaine in the office, you have to use it within one hour's time, from the time you prepare it to the time you inject it.

We were able to get it moved to a four hour window, which helps you a little bit, but still not very much, because many offices actually have been using it probably for several days, because it's

good for quite a few days. So we are actually working with USP. In studying, we have to do this special testing, which basically they inject bacteria into the buffered lidocaine, to see if it grows.

And so the early results are promising. So we're hoping that if this testing is fully successful, and then there's a separate set of tests, called stability testing, has to be done. And if we do get that, which means that the lidocaine with epinephrine is stable for a certain amount of hours or days, then we will get what's called a monograph,which would say that if you use this type of buffered lidocaine, prepare it in a very specific way, then you might be able to keep it longer than four hours.

M. LAURIN COUNCIL, MD, FAAD: So why does this matter? Is USP a governing body? Or does legislation follow? Why is it important that we follow their guidelines?

GEORGE J. HRUZA, MD, MBA, FAAD: Well, USP is actually a private, nonprofit organization. And the AAD has been successful in going forward, we actually were able to get a seat on USP going forward. And we also have Dr. Vidimos on the Committee on Compounding.

M. LAURIN COUNCIL, MD, FAAD: And she's a pharmacist, isn't she?

GEORGE J. HRUZA, MD, MBA, FAAD: And she's a pharmacist, as well. So she's been very helpful. And that's I think a big reason why we were able to get at least that initial expansion that I talked about, the monograph. So even though they're not a government body, their recommendations are in legislation, meaning the FDA, for example, is required to follow what the USP determines.

So they're kind of, I call it almost a quasi-governmental body. And already, several states have already adopted the 797, with the four hour rule.

So the big issue is that now pharmacists or pharmacy boards will actually be able to come into your office, to inspect your office, to tell you how to practice medicine, which we find very disturbing. And we are trying to, state by state, say that if you are going to do this USP requirement for the offices, it should be regulated by the Board of Healing Arts, not by the pharmacy board.

M. LAURIN COUNCIL, MD, FAAD: That seems more appropriate. Well, I'm glad we're at least making some progress, four hours is better than one. And hopefully, we can come to some conclusion that is helpful for everyone. Another issue that I've heard a little bit about, which may not appear to be relevant to dermatologists but actually it is, is the issue of surprise billing. So can you tell us a little bit about what surprise billing is and why it's important to dermatology?

GEORGE J. HRUZA, MD, MBA, FAAD: Sure. Well, surprise billing is very hot in Congress right now. And what it usually deals with is a patient goes to an emergency room or to a hospital for some procedure, where the hospital is in their network, yet the anesthesiologist or maybe the emergency room doctor is not in network. And so then the patient gets a bill from those physicians, which may be significantly higher and they would suddenly have much more out-of-pocket cost because they would have to use their out-of-network benefits.

-And there have been some excessive abuses. There was one anesthesiologist in New York that billed a patient $100,000 for anesthesia services. So Congress is very interested in this. And so we've been supportive of some of the legislation, which basically holds the patient harmless. So they're just going to be subject to their usual co-pay deductibles, co-insurance. And then it's supposed to be agreed between the insurance company and the physician.

The problem is that the current legislation that seems to have the most legs in Congress would set the rate to the out-of-network physician at the median in-network rate. And by doing that, you would eliminate really any reason for a plan to have physicians in their network or to

negotiate with physicians, because out-of-network, they're going to have the same rate. And on top of it, they can narrow their network, reduce their payments, so the average goes down.—

So overall, you're going to have, it's going to be a race to the bottom. Now, it doesn't at this point affect dermatologists. However, when the CBO, the Congressional Budget Office, looked at it, they saw $9 billion of savings for the government by doing this. So if this passes in the current form, it's going to become irresistible for the government to say, "Well, why don't we apply this to all out-of-network services across the country, such as dermatologists who are not in their network?" And then again, you'll end up with a race to the bottom, with potentially collapse of the whole private fee-for-service system.

So it's a really important issue. And we do have friends in Congress, some of the physicians in Congress who are recommending a different version of the bill. And we're hoping to make progress there, which would basically set the rate at some more reasonable, such as some measure of usual and customary fees, or some other third party measure.

M. LAURIN COUNCIL, MD, FAAD: Well, I certainly hope that we come to a solution for that. There are also some changes within derm path reimbursement recently, correct?

GEORGE J. HRUZA, MD, MBA, FAAD: Yes. So we have issues, this gets more into the specific insurance company issues. And so we have one of the major insurers in a number of states, including Missouri, has notified the dermatopathologists that take care of, you know, they could be dermatologists or dermatopathologists, basically those that provide dermatopathology services, that they would be getting paid at about a 50 percent rate of Medicare rate, 50 percent, one-half.

Which, as I think most of us know, is totally impractical and not do-able. And the end result will be that all those lives will have to pull out of that plan and they will have to send their… the

dermatologists will send their pathology specimens to the big national labs, which have lots of issues with them because you don't know who is going to be reading your slides. It's maybe a different person each time. It's not so easy to communicate with them. You need dermatopathology correlation for difficult melanocytic lesions.

M. LAURIN COUNCIL, MD, FAAD: I agree.

GEORGE J. HRUZA, MD, MBA, FAAD: And some inflammatory diseases. So it's really going to have a negative impact on patient care. So we are making every effort. I'm just suggesting that if you're in that area and you are aware of that, if you find that there is, if you have any comments to make to the insurer, I think it's a good time to speak up and let your concerns known about it. Because so far, we have had very little success in communicating our concerns about how it's going to affect quality of patient care.

M. LAURIN COUNCIL, MD, FAAD: Thank you. Another issue that we've seen recently is the issue of Modifier 25. It's the modifier that we use when we do a procedure on the same day as an office visit. Tell us what's happening with regards to this modifier.

GEORGE J. HRUZA, MD, MBA, FAAD: Well, I can start with the good news. We've had incredible success, a huge win, probably the biggest win we've had in a number of years, which is that last year, CMS had recommended to pay only 50 percent on the E&M visit when you do a procedure on the same day, with the Modifier 25. And through working with our allies, , CMS decided to basically put it back on the shelf. Meaning they are not going to be touching it, they lost interest in that area at this point.

So that's been a huge win. However, some of the plans continue trying to make some sort of, a little bit of end runs around it. So a few plans in the East Coast still have this cut that they do. So we're still dealing with some of that. All the other ones that were going to do it, Anthem, United

Healthcare, there were a few others, they basically all backed off. Now that CMS has backed off,

However, they've come up with another interesting twist on it, is that they say if you have two visits within about two months of each other, and then you do a procedure on one of those visits, and they're all with the same diagnosis, same or similar diagnosis, then they will not pay for the visit with the procedure. So think of someone who's getting ultraviolet light therapy and they get seen every certain number of visits, as you're supposed to see every certain number of light treatments, they are not going to pay for that visit for the light treatment.

Fortunately, that affects a small number of situations, as opposed to the general Modifier 25 issue, so I think I feel pretty good about overall we've done well. And, of course, I'm just going to put a plug in right here because the Modifier 25 issue and then another related issue dealing with global periods, which we also were able to save for a number of years, is that those would not have been possible if people were not engaged, involved, which allows us to get that access we need in order to make our case.

M. LAURIN COUNCIL, MD, FAAD: Well, we all have busy practices and maybe not everyone can take time to get as involved in advocacy as others, but we certainly can contribute financially and have someone do that on our behalf. One issue that many patients have brought up lately during office visits is the issue of safety of sunscreen, both for the patient and also for the coral reef. And sometimes sunscreens have been outlawed in certain areas or banned. Tell us a little bit about what's going on there.

GEORGE J. HRUZA, MD, MBA, FAAD: So the sunscreen issue has really been in the news a lot. And there are two components to it. we have not had a new sunscreen in the United States approved in decades. And so it was designed for that.

However, what happened instead, two years later we have no new sunscreens, , which is very challenging because all these ingredients are generic. So which company is going to want to spend millions of dollars to go through this testing? And then on top of it, the FDA decided we should actually have the sunscreens that are currently on the market, the chemical sunscreens need to undergo the same type of testing or they might have to be pulled off the market.

So that put a lot of scare into people. They didn't say they're unsafe. But the problem is when they said, "Well, you should be looking at this." And then on top of it, then they published the paper saying that these chemical sunscreens are absorbed in the bloodstream, then patients were getting all worried, even though there have been no health effects ever, significant health side effects been seen in the last 40 years, since these have been used. So it's all very challenging for keeping patients getting sunscreens, putting their sunscreens on. Yet, they say, "Well, but is it safe?"

So that's a big kind of communications struggle. So that's really part one. And what we're doing is we're working with the FDA and actually trying to get them to get together with the sunscreen industry, in order to figure out a way to get these tests done, so that it becomes more practical. So that's part one.

Now, part two has to do with the coral bleaching issue. So there were some studies in labs showing that if you have a high enough concentration of chemical sunscreen, oxybenzone and there's one other one, I always block on the name, but oxybenzone is the one you see the most, use the most, because it's the most effective UVA/UVB filter we have. So if you use a high enough concentration, if there's enough of that in the water, that seems to contribute to coral bleaching.

And because of those studies, there have been a couple of bans in Hawaii, Key West, and the U.S. Virgin Islands, two of them are in 2021 I think, the U.S. Virgin Islands may be sooner. And

basically, they won't be able to sell them. U.S. Virgin Islands, you'll get fined if you bring them into the U.S. Virgin Islands. So it's becoming an issue. A couple of other places have defeated those pushes for the bans.

And there was a study that just recently, a very detailed study just was recently published, showing that the levels of those chemical agents in Hawaii, near the corals where swimmers are swimming with those sunscreens on, is less than – is more than a – it's one magnitude lower than the amount, the minimum amount needed to cause coral bleaching. So at least in current use, that does not seem to be causing a problem, or it doesn't seem to have a potential to cause a problem because the amount in the water, even where there are people with those sunscreens, is so low it would not be able to cause damage to corals.—

The biggest threat to coral is that global warming has been established as being the biggest threat. So we are right now, our advocacy efforts are to recommend that any places that consider these bans of sunscreens, they should really consider the science that's there on corals, but also weigh it against the fact that we know that sun exposure does cause skin cancer and patients die from skin cancer.—

So we have a definite threat here, that we know we can reduce by using good sunscreens. Again, something that is very uncertain at this point. So our recommendation is to really wait until there is more science, to say one way or the other.

M. LAURIN COUNCIL, MD, FAAD: I agree. And patients who are particularly worried about this, I always advise them there are other ways to protect your skin, too. If you're really worried about using this and harming coral, wear sun-protective clothing, avoid the sun during peak hours of the day, maybe try a physical blocker instead of some of the chemical sunscreens. And most patients are pretty open to those suggestions.—

So we've talked about a lot of different things that affect dermatologists. What can the practicing dermatologist do to help? How can they be involved?

GEORGE J. HRUZA, MD, MBA, FAAD: Well, it's actually very important to be engaged and involved. Because we have a very good Washington staff, but without the dermatologists helping out, it's very challenging. So you can start out very easy. When you get one of these AAD alerts, telling you to email your congressman, congresswoman for some specific issue, it's very easy, it's really only a few clicks. Ideally, you can put a little personal story into it, you can basically click in the email and it just automatically just gets everything going very easily. You can really literally do it in about 10, 15 seconds. So that's the first one to do.—

Next up of course is come to the Legislative Conference, we have that every year in September, it's the second week in September. It's a lot of fun, actually. You'll learn a lot but you'll also then go and do some grassroots advocacy, to meet with your congresswoman and their staff, congressman and staff, to make an impact.—

Well, I've been very successful because I got my daughter to be an intern in my congresswoman's Washington office. So that's probably even better than the cell phone number. So anyway, I just think it's really important to be involved because then when there's an issue that comes up and you give them a call, they'll take your call. So that's what's so important.

M. LAURIN COUNCIL, MD, FAAD: Well, you've certainly given our listeners a lot of different things to think about. We had a great update on all the advocacy efforts that are going on. You've also kind of inspired us to get involved a little bit more.. Thank you very much for your time. Are there any concluding thoughts with which you'd like to leave our listeners?

GEORGE J. HRUZA, MD, MBA, FAAD: As I said, be engaged, be involved, get involved with the Academy. Because we've got your back but we need your help to achieve all the great things we've been able to achieve so far.

M. LAURIN COUNCIL, MD, FAAD: Well, thank you very much, Dr. Hruza.

GEORGE J. HRUZA, MD, MBA, FAAD: Thank you.