



- Speaker 1: Welcome to the *ASHPOfficial Podcast*, your guide to issues related to medication use, public health, and the profession of pharmacy.
- Mindy Burnworth: Thank you for joining the ASHP Advocating for Impact podcast, where every episode covers a policy issue impacting the practice of pharmacy. We will do our best to translate the politics and the legal lingo to help you understand how these issues affect your practice and your profession. I am Mindy Burnworth, PharmD, fellow ASHP, fellow Arizona Pharmacy Association BCPS, Full Professor at Midwestern University College of Pharmacy in Glendale, Arizona. I have special interests in adult internal medicine, rare diseases and advocacy.
- Janet Lee: And I'm Janet Lee, Operations Manager at the Johns Hopkins Hospital, Weinberg Oncology Division. We are recording this at the 2019 Midyear Clinical Meeting in Las Vegas, and today we're guest hosting this podcast. As pharmacists, we don't really have a lot of visibility into how lobbying and advocacy on behalf of pharmacists happens. So today we're going to turn the tables on our regular hosts, ask ASHP's government relations team to give us an inside perspective. I'm here with Tom Kraus, ASHP's Vice President of Government Relations, and Doug Huynh, ASHP's Director of Federal Affairs.
- Mindy Burnworth: Well, let's dive into our interview. So Tom, I'm going to start with you. We are curious about your background and how someone becomes a government relations professional. What was your path to ASHP's government relations team?
- Tom Kraus: Thanks, Mindy. I think people come to government relations roles from a variety of backgrounds. I happen to have a background in public health and law, I started working in the United States Senate as an advisor to senators developing healthcare legislation. I worked on issues like the Affordable Care Act and issues impacting FDA oversight of food and drugs. And then I worked at the FDA, leading their team that engages with Congress. So that included things from negotiating legislation on behalf of the agency to preparing for hearings before Congress to managing oversight investigations from Congress. I've also worked in the public sector on issues like helping Medicaid programs reform their payment models to encourage primary care.
- Mindy Burnworth: You definitely have a rich background with politics and political advocacy. So Doug, do you have a similar story?
- Doug Huynh: So I've got a similar background to that of Tom's. I'm a registered lobbyist. I've been lobbying for about 20 years now. The past 15 years prior to working at ASHP, I led lobby for a physician organization. And quite honestly, I don't think anyone really goes into lobbying with the intent of originally doing that.
- Doug Huynh: My background was essentially when I was in my third year of law school had interest in lobbying and I had an informational interview with one of the partners at Patton Boggs, which is one of the bigger lobbying and law firms in Washington, DC, and said, "What does it take to be a lobbyist?" He said, "You need one of two things." He said, "Number one, need to have a lot of contacts on the Hill, and number two, you need to know an issue really well." So I left that meeting and I thought to myself, "Well, I don't know anybody on the Hill and I don't know anything. So I guess I'll practice law." I did that for a while. And an opportunity came up where I found a job at a think tank organization, working for Jack Kemp and Bill Bennett. And from there I moved on to this physician organization and I'm now here at ASHP. I'm really enjoying my time here.
- Mindy Burnworth: Thank you for sharing your backgrounds. I know as pharmacists we often have various reasons why we get into pharmacy, and I would like to think that all of us got into pharmacy for the impact that we could have on direct patient care. So our ins and outs of daily life is really focused on providing the best patient care. So as pharmacists, we don't often get to directly engage in the federal policy-



making process. So Tom, let's go back to you. Can you share with us, what does a typical day look like for you as you advocate for policies that are impacting pharmacists, that ultimately can impact patient care?

Tom Kraus: Absolutely. Yeah, the days can vary pretty substantially, and it depends what type of issue we're working on. So we work with ASHP's members, identify experts in different topic areas who can serve as an expert to attend forums and educate public policymakers, whether that's members of Congress or folks running healthcare agencies. We assess bills, pieces of legislation that seem to have an impact on pharmacy, and spend some time working with state affiliates that are themselves analyzing legislation to help them digest and understand the impact that those bills are going to have on pharmacy. I spend a lot of time engaging with regulators as well. That's a little bit different than engaging Congress, so agencies like the FDA or EDA or CMS, which is responsible for the Medicare program.

Tom Kraus: And then I think the thing that a lot of people don't realize is how much ... spend developing coalition. So for me in particular, I spend a lot of my time reaching out to other organizations, hospitals associations, the AMA, certain clinical specialties. We do a lot of work with anesthesiologists and clinical oncologists, and using the relationships with those groups that have a similar interest on a given topic to build a coalition because it's much stronger when we go have a conversation with a member of Congress if it's not just us, but a group of clinicians, a group of potentially patients, maybe even healthcare insurance companies. It depends on what the issue is, but anytime you can bring a broad [inaudible 00:06:24] to an issue, it's much stronger. So that's how I spend a lot of my [inaudible 00:06:28]. Doug has a very [inaudible 00:06:30].

Doug Huynh: Right. So as Tom alluded to, it kind of starts with an idea, so whether that be something we hear from folks on the Hill or regulatory agencies like CMS, or some issues that we might just hear from some of our colleagues in the healthcare field. And from that point, what we basically do is we put together a strategy plan of action. So just as an example, obviously with drug pricing being a key topic the past few months, we tried to identify what are some of the key issues and concerns that ASHP has in regards to direct pricing. We talked to a lot of folks within the membership. We talked to some of our colleagues on staff at ASHP. We developed a strategy. And then from that point on, our job is to essentially educate folks on the Hill, educate folks within the regulatory realm, whether it be CMS or the FDA, and essentially advocate, or in other words, lobby for a particular issue of concern.

Tom Kraus: I'm just going to build on something Doug said. A lot of times we are reacting to legislation that is being contemplated by policy makers. But just often, we'll hear something on the practice side that's coming from pharmacists to say, "Hey, this is an issue. We're not really sure what the policy solution is, but this is impacting our practice and we need to come up with an approach that's going to help address this issue."

Mindy Burnworth: I'm so glad that you brought the ideas back to the daily practice of the pharmacist and the value that you have in asking us what are the struggles that we have? What is impacting patient care at the local level? And one of the other things that you mentioned that really kind of struck home for me was this idea of a coalition. So one of my favorite quotes is, "Alone we are rare. Together we are strong." And I hope through this podcast that we're all going to get a better flavor and understanding for the impact that our voice, the pharmacist's voice, can have on Capitol Hill.

Janet Lee: So can you guys give us a few more details on how exactly you go about solving policy problems?

Tom Kraus: Yeah. So we talked about having conversations with members of Congress, and that's certainly where Doug spends his time, and he can tell us about that. But often the issue doesn't actually require [inaudible 00:08:55]. A lot of times there are issues that come out of regulatory agencies like FDA



and CMS or DEA, where they've proposed a new regulation and they may not have fully understood the impact that would have on practice. There may be some things happening out in the market that those agencies aren't aware of, and they just need to be able to provide us more input and guidance on how to respond. A couple of examples that I can think of that happened like that were, for example, several hospitals let us know that they were having a hard time getting access to Suboxone. And that was a result of something that DEA had done. And several of the wholesalers are interpreting DEA's guidance in a way that prevented certain hospitals from [inaudible 00:09:47].

Tom Kraus: And so that really came down to simply learning about the issue, reaching out to the DEA, going and having some conversations with them, educating them on the issue why it was a problem, and actually helped to solve that. And within a couple of weeks they were willing to get on the phone with the suppliers, explain the issue, and that issue was resolved and hospitals [inaudible 00:10:09]. So that's kind of the easiest situation, but that's dependent on having a good working relationship with those agencies, and knowing how to get ahold of them.

Tom Kraus: Other issues require a little more engagement. So something else that's kind of active right now is DEA quotas for opioids, and the impact that that can have on shortages. So this is an issue that is concern for us. We understand the intent of the agency, but what we've done is we've worked with other groups including the AMA and AHA to reach out to the DEA as a group and let them know where we have concerns, and have some conversations and kind of learn about that quota system, how we can improve it and how they can work better with manufacturers to make sure that at the end of the day pharmacies get the product they need.

Tom Kraus: Another issue where we've taken this kind of approach, and this kind of a multifaceted approach, is around CMS funding for residency programs. I know this is a hot issue right now. We could probably talk more about it. And our approach there has been to work directly with the agency, educate them about the value of pharmacy residency programs, educate them about some of the challenges that residency programs are seeing right now. And hopefully, we'll get to a good place with the agency that'll resolve some of those issues. But we've also taken a direct congressional lobbying approach on that particular issue. Maybe Doug can say more about that.

Doug Huynh: Sure. So for this particular issue the actual ask that we have for members of Congress isn't necessarily a legislative ask. It's more of a political ask. In this particular scenario, what we're looking to do essentially requires CMS to give us a little more clarification on a particular issue with some technical assistance. And so the approach that we took in this particular scenario is that we essentially went to members of Congress and asked them to lean a little bit on CMS to kind of expedite that process. And so that takes form of either a letter, a phone call, email, hopefully a combination of all three. And so again, the desired result of that particular ask is for them to get on CMS and to encourage them to help us achieve our ultimate goal. So again, that's one example where you kind of combine some of the regulatory issues with the legislative.

Doug Huynh: And one thing I think we should keep in mind when we're talking about advocacy and lobbying is that when you're looking at an agency such as CMS and the FDA, they're a regulatory body, so they don't create the law. So as an example, if you want to change the actual statute and the actual meaning behind a piece of legislation, obviously, you go to Congress. Regulatory bodies basically are only there to enforce the actual piece of legislation. So it's kind of like a two-fold thing and a two-fold process. And the approach is a little different in regards to how we approach folks on the regulatory side as how we approach folks on the legislative side.

Janet Lee: So you guys have touched upon ASHP members bringing items to your attention that they wanted your help and guidance from ASHP. And also the fact that you guys reach out to pharmacists to kind



of get the insider's opinion on how these policy issues are impacting us on the ground. Can you guys also tell us how practicing pharmacists make an impact in advocacy?

Doug Huynh: One of the key rules that we ask of you when you're getting involved in advocacy is two things. Number one is for you to also be an expert clinical expert for us. An example of that is, I think Tom might've mentioned earlier, one of the issues that we're pressing on the Hill is to put together a piece of legislation that would enable pharmacists to be considered eligible providers for the [inaudible 00:14:12] process and to administer and manage MAT. One of the questions that I often get asked on the Hill, as an example, is, "Okay, so you want your members to be able to prescribe and manage buprenorphine. What about some of the clinical effects of the drug that might come into play as opposed to weaning them off of opioids? What if they get hooked on buprenorphine?" And so that's something that I as an advocate and as a lobbyist I'm able to answer. And so your expertise, when it comes to things like that, is helpful. We've had folks come to the Hill with me on some of these meetings and they kind of explain from that clinical perspective.

Doug Huynh: And the other role that you play is as a constituent. So a lot of times what we try to do is we try to get you involved at your local district or have you come into DC during the fly-in to basically let them know that you want your voice heard as a constituent. And as you can probably tell, that's a really key factor in getting them to listen to us as an organization is when they actually have their constituents present.

Mindy Burnworth: Tom, Doug and Janet, that's all the time that we have for today. I look forward to our next interview together. And just to pull together some of the key concepts that we've talked about with advocacy, it sounds like we need to be taking a proactive approach in developing relationships with our regulators now and also maintaining those relationships.

Speaker 1: Thank you for listening to *ASHPOfficial*, the voice of pharmacists advancing healthcare. Be sure to visit ASHP.org/podcast to discover more great episodes, access show notes, and download the episode transcript. If you love the episode and want to hear more, be sure to subscribe, rate, or leave a review. Join us next time on *ASHPOfficial*.