



006. Drug Pricing: A Conversation with Tom Kraus and Doug Huynh *Episode Transcription*

Speaker 1: Welcome to the ASHP Official Podcast, your guide to issues related to medication use, public health, and the profession of pharmacy.

Tom Kraus: Welcome to the ASHP Advocating for Impact Podcast, where every episode will cover a policy issue impacting the practice of pharmacy. We'll do our best to translate the politics and the legalese to help you understand how these issues affect your practice and your profession. I'm Tom Kraus, VP of Government Relations for ASHP, and with me today is Doug Huynh, Director of Federal Legislative Affairs, and Doug's our lead federal lobbyist. Welcome, Doug.

Doug Huynh: Hi, Tom.

Tom Kraus: So today, Doug and I are going to have a conversation about drug pricing. As you may be aware, this is an issue that has been really at the top of the agenda for a lot of members of Congress and other policymakers. Certainly, it was one of the main issues in the previous presidential election. It's come up again this election season. I think we're going to be seeing more of it, and this is an issue that impacts all of our patients.

Tom Kraus: On the outpatient side, patients are directly impacted by a lot of the cost-sharing associated with drug prices, and patients may choose to discontinue therapy due to drug prices. Drug costs also have a huge impact on hospital budgets. Earlier this year, the Federation of American Hospitals and ASHP together, released a survey of how drug costs impact hospital budgets. What we learned was, the average total drug spend per hospital admission was up 18.5% over the years 2015 to 2017. Growth in inpatient drug spend exceeded Medicare reimbursement updates five-fold in the study period. There were several classes of drugs where the increase exceeded 80% growth, and that included some anesthetics, parenteral solutions, opioid agonists, and chemotherapy products. The impact of those budget expenses is that one in four hospitals report having to cut staff in order to manage those budget impacts related to drug prices. This is certainly something that impacts our profession and pharmacy and hospitals generally.

Tom Kraus: It's important to note that now, hospital reimbursement does take drug costs into account, increases in DRG payments and payments from commercial payers, they have a lag. So if there's a drug price increase in the near term, that means that the hospital's budget is eating that costs. So Doug, this is a big issue for ASHP members and for hospitals. So we wanted to talk about just what are the policy options in this space. What do you think is likely to happen, and how's ASHP engaging on this issue?



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Tom Kraus: We started this year thinking that drug pricing was going to be maybe the one bipartisan bright spot. In fact, during our conversation at the summer meeting, we had a conversation about how we expected drug pricing legislation to pass hopefully by the fall, and that hasn't been the case. There's been some progress, but we haven't gotten there. Can you tell us a little bit about kind of some of the initial bipartisan efforts around drug pricing legislation, and how are those fairing today?

Doug Huynh: Sure. So as you mentioned, drug pricing has obviously been a pretty big topic for the 116th Congress. And as you recall during the 115th Congress, opioids was kind of the flavor of the day. As we mentioned in the summer meetings, drug pricing legislation has pretty much ramped up in 2019. I believe through the course of the year, we've had close to a dozen hearings on both the House and the Senate side in regards to drug pricing. We had mentioned some of those pieces of legislation during the summer meeting. We talked about bills, such as creates pay for delay, 180-day exclusivity, which you can probably get into a little later. A lot of those bills, for the most part, were fairly bipartisan. As you may recall, things kind of got kick-started in May of 2019 when the House introduced and passed a pretty comprehensive healthcare bill with a lot of drug pricing legislation in that. The Senate followed up a few months later with the Senate health bill, which included some of the same provisions that the House bill introduced in May.

Doug Huynh: Then, finally Senate finance introduced the bill in September. That included a handful of those provisions as well, but it also included some things that were left out of the previous two iterations of legislation. Most notably, I would say the most controversial piece of that would be a provision which would require drug companies to basically pay a penalty if their drug prices rise faster than the rate of inflation. One of the other things we talked about, which we can also get into a little bit later are some of the more controversial aspects of drug pricing that aren't necessarily bipartisan. What comes to mind most noticeably is the House provision in regards to Medicare part D negotiations.

Doug Huynh: I want to say as a general caveat, one of the delicate issues when it comes to both the House and the Senate in regards to Democrats and Republicans is that you also have to make note of the fact that president Trump and the administration wanted to make drug pricing legislation one of the key points of his campaign. So there has been some talk politically that members within the Democratic party didn't necessarily want to go all in, so to speak, when it came to drug pricing because they didn't want to necessarily get him a, "win." And so again, please keep that in mind when we're trying to address where we are right now when it comes to the whole landscape of drug pricing within Congress.



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Tom Kraus: Yeah. Maybe we can take several of those pieces that you mentioned and just kind of break them down for listeners. So you mentioned the president's engagement on drug pricing. You're right, this has been a theme of, it was a theme of his campaign. It was something that he has talked about really throughout his presidency. And early on, he had released a blueprint to address drug prices. One of the main things that this administration has proposed is linking drug prices domestically to international prices. One of the things that has been proposed is what's called the international price index model and basically what that means, the government would, for Medicare part B drugs, allow independent vendors to pay prices based on a sort of average basket of a bunch of different prices paid in developed countries for those drugs.

Tom Kraus: It's unclear how well this would work, but it is something that has been proposed and it would have substantial savings. I think there was something like \$44 billion of savings initially and up to \$202 billion of savings by 2024. So it's certainly potential for substantial savings. However, there's been a lot of controversy about how that could actually be implemented. This would upend the buy and bill model for part B drugs, which means it could significantly disrupt reimbursement for hospitals. It's also unclear how much of those savings would be realized because this is not actually government negotiation of prices or has been talked about. But it is something that's been proposed and there's a lot of kind of guessing what the president might be doing is using this proposal as a kind of a stick to bring the pharmaceutical industry to the negotiating table to try to work out a legislative approach to drug pricing.

Tom Kraus: So that brings us to what's going on in Congress. As you mentioned, there had been bipartisan legislation earlier this year and that included several provisions that ASHP was supportive of. Can you maybe just give us a little bit of the detail about how ASHP was advocating on drug pricing?

Doug Huynh: Sure. So just to take it a step back, as you may know, two of our key points in regards to drug pricing advocacy involve promoting policies that increase generic competition and preventing PBN from imposing retroactive DIR fees. With a lot of the legislation that we've been in support of, we try to make that a central focus of our efforts. As I mentioned before, there was a handful of bills that we've been tracking and the one thing that I want to reemphasize is that when we're talking about some of these individual pieces of legislation, we support both the individual bill in addition to how those individual pieces of legislation can also be incorporated into a larger package. So the analogy I like to use a lot of times when it comes to how things work in Congress is that if you look at like a medical device company, a lot of times when you have a



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startup company, the entire goal of that small startup company is to basically be bought out by a bigger company.

Doug Huynh: So if you're a small company called, "X, Y, Z Catheters," your goal is basically to be bought up by General Electric. It's kind of like the same line of thinking when you think of legislation. A lot of times with these individual bills, the ultimate goal is to get incorporated into a larger healthcare package to get incorporated into an omnibus package or a continuing resolution. That's kind of where we stand right now. If you were to do a basic search in the congressional database, you see over 90 individual drug pricing bills on the docket right now. A lot of them, to be honest with you, kind of mentioned the same thing. As an example, one of the bills that we're in support of is called, The Fair Drug Pricing Act. And basically what that does is it requires a drug companies to justify to Congress into HHS, the reason for particular drug price increases. Even within that whole concept, you have different iterations of The Fair Drug Pricing Act. You have Phair Drug Pricing Act that's spelled P-H-A-I-R, and then of course the typical spelling, F-A-I-R.

Doug Huynh: So it's one of those things where that's an example of a piece of legislation that we're in support of. Another bill that we're in support of is called The Creates Act, which I'm sure you've heard of mentioning before. This was introduced in the previous Congress. What that basically does is that it helps generic drug companies access samples for drugs at a fair market value price. The penalty for not being compliance with that is, Congress just makes it easier for companies to go to litigation in that regard.

Tom Kraus: And just to clarify for folks who are listening may not be familiar. So part of the reason that that is needed is to get through the regulatory process. Generic companies need access to the basically the innovator product. So one of the ways that they were being prevented from coming to the market was not being able to access those products. This is a way that Congress is saying, "No brand manufacturer, you actually have to make those products available so that a generic company can do the appropriate testing, go through the regulatory process, and have a chance at getting to the market."

Doug Huynh: Right. Again, that goes along the lines of our general policy promoting general policies of increasing generic competition. Along those lines, another concept that you may have heard of is the Pay for Delay tactic, which a lot of companies use to essentially, it's exactly what it sounds like. They literally pay generic companies to put on hold introduction of certain drugs. That's a piece of legislation that we support and that that has been included in several of these larger healthcare packages in addition to



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being introduced as a standalone bill. There's a bill called, The Remedy Act, which addresses the tactic of evergreening, which is basically the practice of filing unfair extensions on patents. Again, this kind of goes into the whole line of essentially brand drug companies coming up with certain measures and tactics to essentially delay and put on hold the introduction of new drugs into the generic marketplace.

Tom Kraus: So this is the kind of practice where at the last minute before some of these products are going to be subject to generic competition, there'll be new patents filed or they'll call it a patent thicket. Basically, they'll file so many patents that even if you succeeded in challenging one patent, you'd sort of can't navigate all the different patents associated with a given product and it basically comes almost impossible for the generic company to navigate those hurdles. So this legislation reduces some of those barriers.

Doug Huynh: That's exactly right. There's a lot of different tactics for that. There's another tactic they use called, a citizens' petition. The FDA allows you to essentially kind of, I guess protest is the best word for it, to challenge a new and upcoming patent through means of a citizens' petition. So we haven't formally gone on record as supporting or opposing this practice, but this is a, again, another example of ways that branded drug companies kind of delay the entry of a certain drugs to the marketplace. An interesting stat on that in regards to citizens' petitions and evergreening is you would think that that has a remedy for the average citizen, but I believe the latest stat for 2018 show that over 90% of these petitions were actually filed by drug companies, not consumers. So that just kind of gives you a general idea of where they're going. Congress as a whole, basically wants to stop that practice. So again, we're in support of any remedies that basically kind of curtail that particular practice.

Tom Kraus: So a lot of the different proposals that you just mentioned that we supported were actually included in earlier versions of legislation, both in the House and the Senate. In the House in particular, the House has not been particularly bipartisan, but this actually was an area where there appeared to be bipartisan progress. Can you just give us a sense of the politics? What happened? Why did this become a much more partisan fight?

Doug Huynh: To be honest with you, it became partisan based on various provisions within the direct pricing landscape. As I mentioned to you earlier, if you go back to the House bill in May, it included a number of bipartisan provisions, but one of the things that it also included, which kind of precluded support from the Republicans, that included some provisions in support of the Affordable Care act. So that kind of goes along the lines of some of the political maneuvers that both the Democrats and



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Republicans are engaged to essentially score some political points, to be honest with you, mainly in gear for the 2020 elections. So that is one example of sometimes where politics kind of overtakes policy and it's unfortunate, but you see that a lot. As we mentioned before, if you look at the majority of the legislative provisions in both the House and the Senate bills, for the most part, they've received bipartisan support.

Doug Huynh: It's little things here and there that kind of leave somewhat of a hurdle in that regard. Another example of that is, if you look at the Senate HELP bill, again, it includes a lot of the same provisions in the House bill that was passed by the House Democrats, but it also included a fairly controversial provision called, surprise billing, which basically tries to exempt the beneficiaries from paying surprise out-of-pocket costs in an emergency situation. That has become a political firestorm in the sense that, that's something that's not necessarily supported by a lot of Republicans. So again, you're running into one of those situations where the politics sometimes gets in the way, and so that's where you see that divide sometimes between partisan and bipartisan ideals.

Tom Kraus: And just for folks who are not familiar with some of this terminology there. So when Doug mentioned the HELP bill, that means there's a committee in the Senate called the Health Education Labor and Pensions Committee, the HELP committee. That committee is responsible for all public health-related legislation, as well as insurance regulation in the private market. Then there's another committee called the Finance Committee, which is responsible for Medicare and Medicaid.

Tom Kraus: So Doug, you mentioned this bi-partisan or the sort of partisan dynamics there, and you even mentioned sort of some of this is actually intended to sort of force the other party to take some hard votes. We saw that with Democrats including some ACA related language in their drug pricing bill, basically to force the Republican colleagues to make a hard decision about do they support drug price legislation and if so, are they willing to support some ACA related provisions? It made it sort of intentionally put them in a bind and as a result, the legislation was no longer bipartisan.

Tom Kraus: It's interesting that even within parties we see some fracturing. So I think several members of Congress on the Republican side are concerned that because this drug pricing issue has been such a priority for the president, the president may be more willing to accept policies that some of his Republican colleagues in Congress might not. So there's actually some anxiety from Republicans in Congress that the president might sign something that they disagree with. Then on the Senate side, we actually saw some fracturing within Republican members of the Senate where Senator Grassley had



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a bill that was a little more aggressive than many of his Republican colleagues were willing to support.

Tom Kraus: One thing that we haven't discussed yet is drug price negotiation. So that's been certainly something that has been, there's been a lot of press coverage about that. I mentioned the president's index pricing model, which is related to price negotiation in that it leverages negotiated prices of other countries. But can you give us a sense of what's going on with this drug price negotiation issue and the role that Nancy Pelosi's legislation's playing here?

Doug Huynh: Sure. So that's a concept that has been floating around for a while now and it actually came to fruition a few weeks earlier in the House's drug pricing bill. As we mentioned earlier, this bill's a little different than the version of the bill that was introduced earlier this May, in the sense that it was just in regards to drug pricing as opposed to just a broad healthcare bill altogether. One of the key components of this particular bill was that it did include price negotiations. The actual provision was named The Fair Price Negotiation Program within that bill. It kind of takes the concept of the international price index and kind of bumps up a level. In this provision, that concept is referred to as the average international price index. What that does is that it lists six countries; Australia, Canada, France, Germany, Japan, and the UK, and it states that a negotiated price for a selected drug may not exceed 120% of the average international price market index.

Doug Huynh: What they're basically saying is that they're trying to use us as a negotiation tool where the Secretary of Health and Human Services can select a certain number of drugs and have the government negotiate the prices of those drugs. In this particular provision, the number of drugs that they are going to negotiate on behalf is 250 of the most expensive drugs to the Medicare and Medicaid system. If you are a drug company and you refuse to negotiate, the penalty for noncompliance is 65% of gross sales, which can increase quarterly up to a high of 95%. So again, that's a tactic that the House Democrats in particular, are trying to use in regards to this drug pricing and landscape. As a general caveat, the partisan aspect of this comes into play in that Mitch McConnell, who of course is a Senate Majority Leader, has already said that this particular concept, this bill, is dead on arrival. Even if and when this passes through the House on the floor, which we anticipate sometime in mid-November, it will probably not even be addressed on the Senate side.

Tom Kraus: So it sounds like the reality is despite a very aggressive policy proposal on drug price negotiation, the reality is we don't actually see a path for that to become law. So if something does move forward, it's likely that it's going to be something that is



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more along the lines of these generic sort of efforts that would reduce barriers to generic competition, maybe reduce total out-of-pocket spending for Medicare beneficiaries and a few similar things like that. Does that sound right?

Doug Huynh: Yeah. You're right on target with that. As you mentioned before, one of the things that the House bills and the Senate bills have in common, aside from some of this open generic market provisions, is the out-of-pocket provisions. On the House side, there's an out-of-pocket of \$2,000 for beneficiaries, and then the Senate side is there's \$3,100. So I can see a scenario where they ultimately sign on the smaller package that include some of those provisions. However, I will say that the one wild card is the fact that President Trump is endorsing certain aspects of price negotiation. Even when the Senate finance bill, he basically came out and said that he supports a Senate finance package, which is of the two versions between Senate HELP and Senate finance is the more controversial of the two. Again, as we mentioned, largely because of the price inflation provision.

Doug Huynh: Just to give you an example of how controversial that is, even though the Republicans have a majority in the Senate, that bill only passed 19 to nine with nine Republicans opposing that Senate finance bill. So I do see a scenario where they ultimately just kind of narrow down the package somewhat. But again, it is really tough to say what's going to happen in regards to price negotiations because if that's something that the president and the administration really pushes for, you might run into some political obstacles. But for the most part, if I had to answer right now, I would say that it's somewhat of a long shot to include price negotiations in the final package.

Tom Kraus: What do we think is a realistic timing for this? I mean, earlier, we thought maybe we'd have something by it this fall. That's clearly not going to be the case. Now the Congress is talking about impeachment investigations and so forth that are presumably going to take up a lot of time. Is it realistic that we're going to have drug price legislation this year or do you think this is going to go into next year? How do you think this gets resolved?

Doug Huynh: If you were to have asked me in the summer, I would have told you that there's a decent chance that they address this year just because it's a great campaign platform for both Republicans and Democrats to go home to their districts right before things gear up for the 2020 election and say, "We kind of fixed drug pricing." But the reality of course, is that number one, it's October 30th right now and including today, you have less than 28 legislative days left on the calendar, more so on the Senate side than on the House side. Be that as it is, there's still a lot of issues left on the table that they have to address aside from drug pricing.



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Doug Huynh: You have to recall that the current continuing resolution expires November 21st. In theory, if they don't address that whole budget resolution process, the government's going to run out of money. So that's one thing that can impede the progress when it comes to drug pricing. Another thing, as you mentioned earlier of course, is the impeachment process. Tomorrow, the House is going to hold its first formal vote on impeachment. Basically, just kind of laying the ground rules for exactly how the process is going to be played out. But it's significant because it's going to be the first time that they're going to publicly go on record as to whether or not they support or impose impeachment.

Doug Huynh: The one thing you have to realize about that is on the Senate side, Mitch McConnell has already indicated that if and when the president does become impeached, that he will take a minimum of five weeks to go through the Senate trial to determine whether or not he's actually removed from office. So if that does occur and based on the way things are looking right now, it seems like it's almost inevitable. Things will basically just kind of shut down for the remainder of 2019. So I'd say the best case scenario is something gets done maybe in a last minute package, such as a continuing resolution. If they have time, maybe something gets done in December. But if I had to bet on it, I would say this probably gets pushed to 2020.

Tom Kraus: Just so folks are clear on that, continuing resolution, what that means is basically that's a way for the government to sort of continue to fund its operations without working out all the sort of nuances of what each agency gets. It basically just kind of continues funding at the current levels. But some of these funding bills often include other provisions related and you could see drug pricing related provision going along with that or moving separately. But I think the main point I'm hearing you say is, at the end of the day, there's not a lot of time left. Congress is getting distracted by all these other political issues. While we think there's some core elements of drug price provisions that we are supportive of that luckily, are being included in a lot of the conversations both on the House and the Senate side, it seems like the reality is we're probably not going to see those provisions passed at best until December, but probably not until next year if at all.

Tom Kraus: Then we're into we're into campaign season and anything's up for grabs at that point. Okay. So where does that leave us? We know that there's going to be these proposals debated. How can ASHP members engage in the process? What would be helpful that members can do to engage on drug pricing proposals, engage with Congress and so forth?



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Doug Huynh: You could help by participating in our grassroots efforts. Again, the fly in that we had earlier in the year was remarkably successful in the sense that every time we go into a Hill office we would basically hear about how much they enjoyed meeting with the members from issues, not only involving drug pricing, but of course things such as the presidency issue and drug shortages, that sort of thing. So I would continue to get as involved as you can.

Doug Huynh: One of the things that you have to also realize is that you don't necessarily have to come to Washington DC to be an advocate and to get involved in the grassroots effort. You can do that locally. As you know, Congress often has recess and during that recess, they welcome folks to come into their local district offices to do the same thing that they would do flying into DC. Another thing you can do is invite them to reach out their members of Congress through ASHP's advocacy tool and send letters of support to members of Congress. You can go on our website, we can basically walk you through that process and just stay involved. Just be aware that they want to hear from their constituents and that's really key and that's something that should definitely not be overlooked.

Tom Kraus: And you can find a link to the advocacy tool that Doug was referring to in the show notes for this podcast. You can also, as Doug was mentioning, you can engage with your own member of Congress in your local community. Especially with all the discussion of health care that's going on right now, a lot of members are having town halls where they're inviting members of the local community to engage with them on health care issues. If you see that opportunity, you should go feel free to voice your concerns to your member of Congress. If you need talking points or sort of ideas for what to communicate, go to our ASHP advocacy website and you'll find some talking points on a lot of these issues and you can use to raise issues with your member of Congress.

Tom Kraus: Well Doug, thanks so much for joining us today and sharing your insights on how this issue is advancing in Congress. I know you're in there every day engaging with members of Congress on behalf of our members and I want to thank you for that. For members who want to learn about this issue, you can look to the show notes for this podcast. You can also go to ASHP's advocacy website and find some key explanations and documents about this issue. Every other Tuesday, we'll be posting a new episode of this podcast where we'll explore other advocacy and policy topics and explaining how those impact the practice of pharmacy.

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