

Dr. Karen Van Nuys:

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Ellen Kelsay:

That's Dr. Karen Van Nuys, executive director of the Value of Life Sciences Innovation program and senior fellow at the USC Schaeffer Center for Health Policy and Economics. Dr. Van Nuys has a wealth of knowledge on the pharmaceutical distribution system and its impact on prescription drug utilization and cost. From uncovering insights on the insulin market to exploring the value of novel disruptors in the pharmacy landscape, she's at the forefront of helping the public and policymakers understand key issues related to the complex pharmaceutical ecosystem.

I'm Ellen Kelsay and this is a Business Group on Health podcast, conversations with experts on the most relevant health and well-being issues facing employers. Today, Dr. Van Nuys and I discuss the pharmacy topics making the news, from recent policy movement on PBMs, the disruptive players emerging, and strategies to reshape the pharmaceutical landscape to promote affordability and access to medications.

Today's episode is sponsored by Color. Color is a complete platform for health care delivery, providing the tools required to distribute large scale health initiatives to dispersed populations. Color's cancer screening and prevention program, in partnership with the American Cancer Society, provides employers with accessible screening solutions, connection to clinical services, high-touch care advocacy, and support to improve health outcomes and reduce costs by detecting cancer earlier.

Dr. Van Nuys, welcome. We're thrilled to have you on the podcast today.

Dr. Karen Van Nuys:

Thanks Ellen. I'm really happy to be here.

Ellen Kelsay:

Well, I am really looking forward to this conversation. Your life's work is focused on the pharmaceutical distribution system and it has been a hot topic of discussion here at Business Group on Health for many years and seems to be getting hotter more recently. There's really so much we can talk about in the course of this conversation, but maybe let's just start at the very beginning about what brought you to this area of work, why is it your focus, and how has it kept you so engaged and interested over the span of your career?

Dr. Karen Van Nuys:

That's a great question. I began my career on sort of more of the business side of things. I was a business school professor for a while and then I went into management consulting and was really more focused on kind of the business questions in the world. Then I got into health economics and health policy work sort of later in my career. This particular topic really lives at the interface of business and health policy. I'm very curious about sort of the business elements that drive behavior in these markets and then the health policy elements about how to make that work better for patients and for payers and for all of us. It's really sort of a bringing together of two streams of work in my career.

Ellen Kelsay:

That's a natural extension, as you said, of that original kind of background professionally for you and I am sure no shortage of continued aspects for you to study in this very complex world that is the pharmacy supply chain. Let's define to our listeners, not everybody is familiar with what we mean when we say the pharmaceutical supply chain or the pharmaceutical distribution system. What is it to the lay person, you know, what is that distribution system? Who are the players? What role do they all play and why do they all matter or do they all matter? Maybe that's a provocative part of that question, too.

Dr. Karen Van Nuys:

I'm sure they all matter in one way or another. In contrast to the way sometimes business people think about supply chain where it's about inputs and bringing together different production inputs to produce and then distribute a product, the pharmaceutical supply chain, at least as concerns the work that I've done and kind of the conversations that are happening now in Washington and elsewhere, are less about where are we getting the raw inputs to produce the drugs and more about once the drugs come off the production line, you know, sort of starting at the manufacturer and then working our way forward, what does the system by which we get those products to pharmacies and then to patients and at the same time get everything paid for through this third party payment system or insurance system. When I think about the pharmaceutical distribution system, it includes wholesalers and distributors, it includes pharmacies, it includes pharmacy benefit managers, it includes health plans and other payers who pay for the drugs we use, and of course, the end customer being the patient.

Ellen Kelsay:

So it's a lot of different entities involved in getting the drug from the manufacturer to the ultimate consumer or the patient. I want to get to your comment about what's being discussed in Washington recently because it's certainly a very hot, very active field from a policy perspective. Before we go there, I wanted to have you define and describe for the audience when we say PBM, who are we talking about? What does PBM stand for and what do they do? What is their role?

Dr. Karen Van Nuys:

PBM stands for pharmacy benefit manager. Pharmacy benefit managers play an important role in this pharmacy distribution system and do a number of things. Pharmacy benefit managers are hired by plan sponsors, employers or other health plans, to do a number of things including back office clearing of transactions and so on, but also things like negotiating prices and discounts with drug manufacturers, designing formularies, creating pharmacy networks that beneficiaries will have access to. Pharmacy benefit managers sit in the middle of this distribution system and talk to virtually all of the players - the pharmacies, the health plans, the plan sponsors, the manufacturers - and collect data from all of those agents to do their work, but that puts them in this very important position. They have a ton of data and a ton of leverage, because of where they sit in the system. The lack of transparency for some of that data has become a big question about how well these markets work if all of the information is going to this central point of leverage and maybe not necessarily being used for the benefit of patients.

Ellen Kelsay:

Thank you for offering that. Within all of these players, within the distribution itself, we often hear that there are an abundant of layers, complexity, some call it opaque, and many would say there are points of friction and that's not very efficient. Would you call out any, in particular, that are especially problematic along that distribution chain that maybe create or compound problems?

Dr. Karen Van Nuys:

Well, rather than focusing on the individual players, let me just give some examples of how it's inefficient or the kinds of inefficiencies we're talking about. This all mostly ties back to the third-party payer system. It's just very, very inefficient to pay for goods through this third-party payer system rather than when you have customers paying directly for the goods they consume. Of course, we need that third-party payment system in the case of you know, health care, and in today's discussion pharmaceuticals, because of the properties of insurance that we actually want people to be insured against the bad health that might befall them. But it is very inefficient in the sense that it does not tend to get products to patients at the lowest possible cost. By example, we did a study a couple of years ago looking just at generic drugs, the 200 most common generic drugs in Medicare, and we compared what Medicare was paying for those prescriptions to what they could have been acquired by customers just going to the pharmacy at Costco and paying cash. We found that on average, just on these 200 drugs, Medicare was overpaying to the tune of about 21%. You can think of that as at least one data point describing how big that inefficiency is, that for somehow involving the payer and the

pharmacy benefit manager in the system increased the cost of these drugs by 21%. There are lots of different places that that 21% might go or business practices that can explain that 21% inefficiency. The overall size of it we can benchmark to about that much, at least in the case of these 200 generic drugs.

Ellen Kelsay:

That's a great example and I appreciate your study and work in that field. We're definitely going to link our listeners to that as a follow-up if they want to learn more. So it's an inefficient distribution system and clearly in that study it's also costly. We often hear the cost of drugs are so expensive, they're not affordable and many times patients aren't even taking their pharmaceuticals because the cost, concerns and challenges, and often it is the manufacturer that catches some of the flack for that, because maybe the drugs are so expensive at launch. While that may certainly indeed be the case, it is not only attributable to the manufacturer that there are all these other entities involved along the various points of the supply chain that are overlaying and creating more complexity inefficiency, and unfortunately more cost. I guess that speaks to the challenge, but it also speaks to the opportunities, perhaps, and as you said, they all have a role to play in helping solve the affordability crisis of the medications. That leads me to maybe the next question that you did allude to earlier, that all of the flurry of activity legislatively on prescription drug pricing and on PBMs most recently. Can you share just at a very high level for our audience what's going on legislatively related to prescription drug pricing, the different players, and in particular more recently the PBMs. Why are they getting so much scrutiny? What is it at a high level of some of the things that you would call attention to the audience?

Dr. Karen Van Nuys:

Yes, historically I'm going to say over the last decade or so, with increasing concerns among legislators, but the public in general over drug costs, most of what we were hearing was focused on the manufacturers that Medicare should be able to negotiate drug prices and that manufacturers were charging high prices. Up until a few years ago, the conversation really kind of stopped there. It kind of ignored the other pieces of the distribution system that we've been talking about. Almost a year ago with the passage of the Inflation Reduction Act, which included some provisions that are now going to enable Medicare to negotiate prices of some drugs directly with manufacturers, it almost feels like that legislation has satisfied some kind of desire to have manufacturers address this. Now I think in some cases the policy attention is moving away from that. They've been focused on manufacturers for such a long time. The IRA put in these provisions to negotiate with manufacturers. Now policy attention is really turning toward some of the other intermediaries in the supply system. Most specifically right now, pharmacy benefit managers are kind of in the cross hairs of federal legislation, which is not to say that they weren't on anybody's radar screen before. They were and certainly states have been out ahead of the federal government in terms of writing and passing legislation that limits what pharmacy benefit managers can do in individual states. But now I think the federal legislation system that Congress has joined in that effort and so now we're seeing this attention turning to pharmacy benefit managers. You referred to this flurry of legislation, and indeed I think there's something like 8, 9, 10 bills currently kind of floating around Washington in various stages of legislation that concern themselves in one way or another with some of the practices of pharmacy benefit managers. Bills vary one to the next in what they cover, but some common elements are increasing transparency in the system so that employers and other entities that negotiate with pharmacy benefit managers have more visibility into the prices that they're actually paying, the cost that they're actually bearing.

There are a number of provisions in a number of bills related to practices called spread pricing, which is the practice of a pharmacy benefit manager reimbursing the pharmacy one price to fill a prescription and then charging its health plan client a different higher price and keeping the difference between those two as a payment. It's called the spread. The spread has been problematic and there have been some studies identifying kind of exorbitantly large spreads in certain systems. One study in Ohio identified their Medicaid system paying spreads averaging 31% on generic drugs and so now there is some energy and legislation around banning the practice of spread pricing and requiring PBMs to charge health plans, whatever it is that they pay the pharmacy to settle the claim. With respect to rebates, drug rebates from manufacturers requiring reporting by the PBM to the health plan on how much revenue they're receiving from manufacturers and then also requiring the PBM to pass through those rebates in their entirety to the health plan sponsor, is another

element of some of the legislation that we're seeing. And then in the case of employer plans, there have been some legislation which includes provisions to better report on or more comprehensively report on the fees that PBMs are paying to benefit consultants who may work with employers to choose PBM contracts or select a PBM to provide pharmacy benefit services to the employer. Those are just a few of the provisions that we're seeing in one way or another across a number of pieces of legislation right now.

Ellen Kelsay:

I'm speaking with Dr. Karen Van Nuys, a health economics researcher, author, and policy expert focused on how to improve efficiency in the pharmaceutical supply chain and ensure patients can afford their medications. We'll be right back.

Color

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Ellen Kelsay:

We talked about policy-based legislative approaches to reform, but we also know that there's a lot going on within the market and we see a lot of disruptors and innovators entering into the pharmaceutical supply chain in various capacities. We would love your thoughts on that. Where do you see disruption taking hold and any great examples of some that are really starting to transform?

Dr. Karen Van Nuys:

I agree. I think this disruption is as exciting as the legislation right now, but keep in mind that this is all kind of stemming from probably the same fundamental dynamic, which is this lack of efficiency, this lack of transparency, this sense that the pharmaceutical distribution system is somehow adding costs that we're not benefiting from and that needs to be changed and fixed. The energy that's driving the legislative efforts as well as these disruptor kind of activities are the same, I think. But to the disruptive activity specifically, there are kind of two areas right now that are especially exciting. There are now a number of small but growing pharmacy benefit manager companies whose business model does not rely on some of the tactics that are so problematic with the larger, more established PBMs. For example, transparent pricing where they set their prices and charge prices to their clients based on identifiable benchmark, external benchmark rather than, you know, some complex formula that's buried in a contract somewhere and difficult to audit and that they pass through rebates to their clients a hundred percent and charge just a flat fee for their services.

There are a number of PBM entrants that are doing this kind of transparent pass through fee-based model as competitors to the larger more traditional PBMs. On the other side in the pharmacy space, we've also seen a number of sort of disruptive models and the most famous one right now is the Mark Cuban Cost Plus Drug Company that started, I don't know, a year and a half ago I guess they launched, but even before that there were some of these cash only pharmacies for generic drugs. The one that I'm most familiar with is Blueberry Pharmacy in Pennsylvania where they charge cash only, they don't take insurance. This is changing a little bit with the Mark Cuban model. They are creating an insurance product at the same time, but when they started no insurance and cash only, but the prices that they charge for this sort of limited set of drugs that they carry, limited but growing, that's based purely on their acquisition costs through a formulaic pricing model where they take the acquisition cost, they add 15%, they add a flat dispensing fee and a shipping fee, and that's how much you pay for the drug.

It's transparent, it's tied to an external benchmark that is verifiable, and it's bringing a lot more sort of sunlight to that market. The sunlight that is brought to that market by virtue of there being a publicly posted price for a prescription that you can go to the web and you can see exactly how much 30 days of this particular medication is going to cost, has sort of blown the lid off of a lot of the opaque pricing that happens inside these traditional kind of insurance contracts where we don't know exactly how the price is set, but when you get the bill at the end of the day it's much, much higher than what you could have paid at Mark Cuban, for example. Simply having that external benchmark to compare the prices that you're paying inside your pharmacy benefit to the prices that are available out in the market is calling a lot of these things to question.

I think the disruptors are exciting. Certainly, patients who are now able to afford their medications when perhaps they couldn't because they faced a high coinsurance or high copayment or whatever, but they can afford them now through Mark Cuban's company, the benefit to those patients is obvious and a great thing. But the thing that's less talked about, I think, is the value of having this public benchmark that now everybody in the market can use to evaluate the deals that they are being offered by their PBM. I think that that value is enormous and I don't think we fully appreciated it up until now.

Ellen Kelsay:

That benchmark is exclusively only pertaining to generics, is that correct?

Dr. Karen Van Nuys:

Right now these disruptor pharmacies are focused on generics, but I will note that I think just last week Mark Cuban announced a deal with a small biopharma company to carry a new SGLT2 diabetes medication, just approved and to carry that at cash prices that are much, much lower than the list prices of other branded medications in that class. I think that little by little we're going to see those disruptor pharmacies make some headway into some of the branded market, but they're moving in that direction.

Ellen Kelsay:

That's interesting. I wasn't aware of that. That's great. We are, to be fair, also seeing some of the traditional players evolve and modify their approaches and doing things like you said, more transparency or pass through rebates, point of sale rebates.

Dr. Karen Van Nuys:

Yes, it's a great point and I should emphasize that we like disruptors for the low prices that they bring to the market, but we really like disruptors for the competitive pressure that they place on all players in the market. That I think is what you're describing, that you were seeing some changes in behavior among some of the established players, in part I would imagine because of the pressure that's being placed on them through some of these more innovative models.

Ellen Kelsay:

You've mentioned this a couple times now, we just have a crisis of affordability where patients, many of them are not taking the medications they need because it is just too costly and all players and the distribution chain have a role to play in really remedying that. We're talking about a couple of good examples here, although those certainly aren't the only ones of opportunities that exist. This really kind of leads me to my question of do you really think we're going to see a change? Will we see a sea change in pharmaceutical costs, affordability of medications? Will the distribution system really kind of modify and evolve in a way that results in those types of outcomes?

Dr. Karen Van Nuys:

I guess I'm an optimist by nature. I do think that some of the early signs that we're seeing point to change. Whether it will result in what you've called a sea change, whether it will dramatically reduce what we spend, I think yet to be seen, but I'm hopeful. I do believe that we are going to see a change.

Ellen Kelsay:

I'm an optimist as well, so I share that sentiment. Let's talk about insulin. Shifting gears a little bit here. Insulin's been in the news a lot over the past year. We see some examples where we've seen some changes in the market, where manufacturers have cut and reduced their list prices making insulin more affordable for the millions of patients that take insulin on a regular basis. So what's going on? What are the forces that led to that development and what are the potential implications and opportunities beyond insulin?

Dr. Karen Van Nuys:

That's a perfect segue from your last question whether we're going to see change. I think insulin is kind of the bellwether here or I hope it is anyway. Just to set some context around the insulin market, we did a study a couple of years ago looking at the flow of money specifically in insulin markets. We looked over a five-year period from 2013 to 2018. What we were able to establish is that over that period of time, over those five years, the list price of insulins was increasing by I think 40%, but the net price that manufacturers were taking home from selling insulin was decreasing by 31%. So there was this gap, this growing gap between the list price of insulin and the net price of insulin. Then the third sort of metric that we were able to kind of tease out of the data was the total amount that we were spending per unit of insulin, so not just what was going to manufacturers, but then what were the margins that were earned by all of those different players in the supply chain that we were talking about, right, the pharmacy benefit managers and the health plans and the pharmacies and so on. All of that added together, so kind of the total social resources that we as an economy are spending on insulin barely changed at all over the five years. What's happening is the total amount we were spending wasn't changing per unit of insulin. What manufacturers were getting was declining by 31% over five years. What that tells me is that all the other players in the distribution system were capturing that difference and an increasing difference over time to the point where in 2018, more than half of what we spent on insulin was going to distribution system intermediaries, not to manufacturers, but to distribution system intermediaries.

When you think of that from the perspective of an insulin manufacturer, you see this market becoming less and less profitable because you see your net prices declining steadily over the course of time. Couple that with, again, the Inflation Reduction Act. There were some provisions in that legislation that capped patient out-of-pocket payments on insulin. The President, I think, in his State of the Union address in January exhorted manufacturers and other payers to do something similar. Indeed, I think it was March we saw, I think Lilly was the one first out of the gate announcing that they were going to dramatically reduce the list prices of important insulin products in their portfolio by, in some cases, 70% cutting the list price by 70%. By the end of March, beginning of April, all insulin manufacturers had sort of made this announcement that they were going to be cutting, dramatically cutting, the list prices of their in these insulin products.

When they did that, I don't have any insight information, but I'm imagining that what must have happened was that they basically stopped paying rebates on insulin. In some cases, those rebates were as high as 80% and they simply lowered their list price to eliminate most or all of the rebates that they had been paying and put a stake in the ground that we're not going to be playing this rebate game on insulins anymore. I think this is an example of the change that we're kind of hoping for or hoping that it is a leading indicator of what might happen in other markets where rebates become a less important part of the equation. I don't have a very good sense of what replaces the rebate system in the negotiations for formulary placement. That hasn't been very well described yet, but I do think that increasingly players in this system are dissatisfied with this rebate system and are looking to change it.

Ellen Kelsay:

Yes, we hear that as well and certainly looking for alternatives to the rebate model. Thank you so much for walking us through all that, that was immensely helpful. All right, as we wrap up, I just have a couple of last questions for you and really wanted to ask specifically about employers and things that you think they should be keeping their eyes on, anything that you think they should be working actively to address within their existing ecosystem of partners, anything that comes to mind there?

Dr. Karen Van Nuys:

Yes, for sure. I mean this is a super exciting time for drug pricing nerds like me. There's a lot to follow, but I think for employers as well, there are many, many things in motion right now. We talked about what's going to replace the rebate model. I think that's a super important question and keeping an eye on what evolves to replace that should be top of mind for many of these players. I think from the perspective of an employer being cognizant of not just the drug spend but the medical spend as well and the impact that drug spend has on medical spend. I've heard this whole system being described as it's like a balloon, you squeeze it in one place and it just gets fat in another place, and that we are putting pressure or legislation is putting pressure on different parts of the system. We've seen the players in the system be pretty agile in responding to those pressures by introducing new tactics or new procedures that skirt the legislation or somehow make up the revenue lost, and so on, so that nothing really changes in the aggregate. I think that as these pressures are getting added now, the temptation or the risk may be that we will see other tactics used to limit drug spend. We're seeing, for example, just an explosion in some cases of the number of drugs that are excluded from formularies altogether, but the number of drugs that are subject to prior authorization or other utilization restrictions, you know, quantity limits or step therapy or whatever, some of the agents in the system trying to utilize those levers more aggressively in order to make up for revenue that they're losing in other places, because the rebates are going away or something like that.

Of course, you know, harsh utilization restrictions or inappropriate utilization restrictions that are purely to save money might save money on the pharma spend, but could very well involve higher medical spend. I would definitely keep an eye on that margin between medical and pharma spend. Then a third thing that I think could be super interesting is in some of the legislation, the draft legislation that's floating around Washington right now, the law calls for pharmacy benefit managers to report more information to plan sponsors about drug prices and drug utilization in their plans and so on and so forth. And presumably that information will be reported in a standardized format. Some of the legislation actually includes language, standardized and machine readable. I think employers could get out ahead of this. That is, if in fact this legislation passes, they're going to be inundated with a ton of information about their plan costs and utilization at a much more disaggregated level than they're accustomed to. Understanding that that may be coming and preparing to actually use that information and make hay with it, that is prepare to read it and compare it and watch it and understand what that information means and how to use it in negotiations with pharmacy benefit managers, how to use it in reducing their own plan spend, and being ready to analyze that data and make smart purchasing decisions with it when it becomes available. That would be another thing I would be looking for as an employer.

Ellen Kelsay:

Wow, you just hit on so many excellent, excellent things for employers to keep their eyes on and to be diligent about and to really be proactive in terms of addressing. I know many employers are paying close attention to some aspects of the things that you mentioned, but maybe not all. Thank you so much for sharing those as great considerations for employers as they move forward with their strategic approach and their vendor management strategies around the entirety of all that we've just been talking about. Karen, thank you so much for the work that you and your team do and thank you for sharing it with us today. Lots to certainly keep our eyes on and lots of reasons for hope and optimism as you said. So once again, thank you for joining us.

Dr. Karen Van Nuys:

That was my pleasure, Ellen. Thank you so much for having me.

Ellen Kelsay:

I've been speaking with Dr. Karen Van Nuys, who holds a PhD in economics from Stanford and an MA from the University of California. Most recently, Dr. Van Nuys has been engaged in research focused on a radical theory, ending insurance coverage for low-cost generic drugs to save patients money. You can find out more about Dr. Van Nuys' research and opinion pieces on her USC profile under <https://healthpolicy.usc.edu/>.

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