Non-Rx Drug Access - ACNU, A Conversation with Paul Wardle, Founder at Beacon Associates

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Episode Highlights

- In this episode, Paul and Rusty discussed ACNU, the FDA's proposed rule facilitating direct-to-consumer access to a wider range of non-prescription drugs
- ACNU aims to bridge gaps in drug access by allowing a new drug application process. The FDA has spent 12 years on this proposal
- Increasing education and awareness empowers consumers to take charge of their healthcare decisions
- ACNU's administration involves various stakeholders, including manufacturers, advocacy groups, and third-party organizations, working collaboratively to enhance medication access
- Payers evaluate ACNU through a cost-benefit lens, considering its potential to avert sequelae and reduce overall healthcare costs. Depending on conditions and products, insurers may cover ACNU medications, requiring ongoing assessment to ensure appropriate use and benefits
- ACNU owns direct communication with consumers. This unique feature enhances the value proposition for manufacturers, allowing them to potentially increase the lifespan value of the consumer
- The Durham-Humphrey Act, defines access (prescription or nonprescription) for everyone based on the drug characteristics. ACNU provides a novel pathway within current regulations to help allow non-prescription access to a particular medication for an appropriate subset of individuals by considering their individual medical characteristics, while others may be required to go to the doctor
- ACNU aims to enhance public health by increasing access to medications by addressing some barriers. The shift is particularly impactful for chronic conditions, potentially improving adherence and, subsequently, healthcare outcomes while benefiting insurance companies and individuals

Episode Transcript

Rusty Ray (00:05):
Good morning. This is Rusty Ray with Alantra. I head up the US Healthcare Investment banking team here in New York, and you are listening to Crossroads by Alantra, our podcast that focuses on the healthcare segment. Today we're going to talk about access to care, specifically access to medication.

(00:21):
In a recent podcast on Rx-to-OTC switch, we delved into the regulatory shift from prescription to OTC. Today we're steering towards a different topic, an emerging regulatory pathway in which pharmaceuticals that focus on direct-to-consumer engagement and access, ACNU, A-C-N-U, the FDA's proposed rule on non-prescription drug products with additional conditions for non-prescriptive use. It's quite an acronym, but the FDA recognizes the advantage of providing patients with access to a wider range of non-prescription drugs, some of which are prescription only. In this episode, we will explore ACNU's impact on drug access, individual medical needs, payer complexities, and public benefits.

(01:02):
Welcome back, Paul. Let's get started. What is ACNU? Break down this acronym for us and give us the lowdown on what it is and how it works.

Paul Wardle (01:10):
Thank you, Rusty. Thank you for having me back. Always good to chat. Great question – what is ACNU. In some ways, I almost want to put the term ACNU aside and actually talk about what its intent is, because the term itself may be limiting in terms of perspectives. But I think where the FDA appears to be trying to go is there's a recognition that our current ways of getting to medicines are somewhat limited because we only have two classes of drugs. We have prescription or non-prescription. There is a large unmet need. So although we have products that are approved and available, they're not getting into the hands of consumers. the intent of ACNU is to find new ways to get medicines into the hands of the people who need it.

(01:56):
And in recognition, as individuals, we're not all the same. It's also filtered based on medical history and medical needs. It is a very different type of solution. It's a new NDA, so a new drug application, which allows a new channel of communicating and engaging with a patient or a consumer directly so they can acquire that medicine in some cases without ever having to see the doctor. In other cases, they will be guided back into the doctor's office because their medical history requires it. So it's non-prescription because not everyone has to go to the doctor in order to get the medication.

Rusty Ray (02:35):
And I guess as with any regulatory change, there's probably an impetus for this. Maybe it has something to do with COVID. Maybe it's the fact that consumers of patients are becoming smarter, and more engaged in their own care. Why now? Why is the FDA taking on this kind of rule change now, which sounds on the surface like a very complex implementation? Who gets drugs when and how? What will the criteria be and who's going to monitor that? Does the FDA feel comfortable that now is the right time for this sort of change?

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Paul Wardle (03:06):
In terms of now, I think now is a relative term when you're writing regulations. They can take quite some years. And in fact, the FDA has been looking at this proposed rule for about 12 years. Some of the factors that have gone into consideration for it are the increase in the number of people having insurance as a result of the ACA, and the incredible gaps in chronic health conditions. So roughly one and two of us, so 50% of us, actually have a chronic health condition, and actually around a quarter have multiple. But when you look across therapeutic areas, many of us aren't receiving treatment. And because we don't have the providers, even if they wanted to go there, we wouldn't be able to meet the needs.

(03:43):
So the FDA is trying to figure out a different way that some people may be able to engage. There are a number of factors – behavioral, financial, geographical, physical. So the FDA is trying to create a mechanism for innovation that allows more people to gain access to the product, responsible access in different ways. And the condition is really undefined of what it needs to be in order to enable that innovation for how we could access medications.

Rusty Ray (04:11):
And the flip side of that is obviously the patient, does that mean that we as patients, as consumers, we're smarter, we're more savvy? It's been often said that people are much more willing to take more charge of their own healthcare outcomes and self-medicate in various ways via OTC or other mechanisms. But I guess I'm just curious because, behind this regulatory scheme, you're relying on an individual to somewhat be smart about their diagnosis, be smart about the management of a chronic condition, and really take ownership of some of these things where maybe in the past we often just follow doctor's orders. So I'm just kind of curious, do you see that there's been a fundamental shift in the consumer and patients that allow this kind of regulatory framework to flourish?

Paul Wardle (04:58):
Yeah, I think you're right in some ways. I wish we were all smarter, but I think as you look at the last 20, 30 years, and particularly with the advent of the internet, our access to information has changed dramatically. Almost since the beginning of the internet, healthcare has been one of the most searched terms. People are interested in themselves. I think that tells you something that they are interested in looking for themselves before they go to the doctor to find a solution.

(05:24):
In some research I was involved in with Klick Consulting last year, we found that around a third of the population would rather do all of their healthcare on their own. Around 40% would rather always go to the doctor. And yet the regulatory framework today as set out by the Durham-Humphrey Act means we only have two solutions, prescription or non-prescription. And that means, sorry, every medicine today is regulated based on the characteristics of the drug. But as individuals, we have different preferences of how we want to engage in our own healthcare. So education has been one of it. As we think about direct-to-consumer advertising, that's been around on medication since about the late 90s. And you see now the way that works is a consumer may figure out, "Oh, I may have this condition," they'll go talk to the doctor.

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(06:10):
But if some of them could actually engage in that process on their own, would we relieve some of the burden for healthcare practitioners? Some of us are relatively simple in terms of our healthcare needs. So the pathway to choose the right medicine may be easier. Others, I'll say heart disease. Let's say you've had a triple bypass, you have diabetes, you've got a higher burden of need, you may need to go to the doctor. So the ACNU rule actually allows us to treat medication by the characteristics of the individual. So those who can self-medicate, self-treat, could get it themselves. Those who really need the assistance of a physician would actually be guided to the physician.

(06:50):
So fundamentally, I think your question, "Are we smarter?" Yes, we're more educated. There's a greater desire to be engaged. We recognize we're looking for simpler solutions for needs that we can do ourselves, but we are also responsible that we know when we're out of our depth in terms of our healthcare needs. And that isn't every situation so we can triage people differently.

Rusty Ray (07:14):
You mentioned a few moments ago various conditions, you said chronic heart disease or others. That leads me to believe that this kind of regulatory framework is not going to be appropriate for everything. You could think of chemotherapeutics or things like that where you still need to go to an office to get an infusion. Or chronic type conditions, whether that's high blood pressure or other types of chronic illnesses. Do those lend themselves to this regulatory framework a little bit better? Or do you see this regulatory framework as sort of opening the door to things where we thought, "Oh gosh, you must go to the doctor to do that." Can we start to take back some of the control within our hands of the consumer of things that were thought of as specialists only?

Paul Wardle (07:59):
Yeah, I think that's a great question and I'm going to break it down into a couple of ways. Firstly, there is a difference for individuals. When you are first diagnosed with something versus have you had a condition for a number of years. So there's an element of the rule that actually says an ACNU can apply to either the diagnosis or for the ongoing use, or for both of them. Let's say a hypertensive medication for a number of years. How could you get easier access to refills? There may be a diagnostic that you have to monitor to ensure that you're still appropriate for the medication. Thus the ACNU may be around some diagnostic measure.

(08:36):
I find it interesting when you said the oncology space, I was thinking about that myself. Would we ever think of this for oncology? And there are certain tests which an individual may not be able to do themselves, but I could get to the place of palliative care. Is there a place where making it easier for an individual to get medication would make sense? I'm not suggesting that that is the solution that everyone should be going after, but I think the FDA, in creating this rule, has tried to leave it open to the innovation of sponsors. They're not trying to replace the healthcare practitioner, but they're trying to enable companies to find solutions that make the journey easier. And we all know in healthcare, adherence across many therapeutic categories is one of the biggest challenges. There's a burden of having to keep going back to get a refill. You may get a different generic each time raising questions of what it is.

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(09:28):
And so I think it does open up the doors. The other piece that has changed in recent history, we now actually have access to our own test results. For many of us, it's through MyChart, through our health provider. But historically that information had to go to the doctor first before we as a consumer could have it. And I think that's a good place for individuals to be more engaged in their treatment options rather than less engaged.

Rusty Ray (09:54):
You mentioned something that I wanted to press on, but you've maybe slightly changed my thinking around this, and that is the sponsor, so the manufacturer, the marketer. How does a program like this get administered? Is it the manufacturer? Is it a third party, say medical adherence type company that's dealing with payers and medication management for lots of patients already? Are they sort of implementing this as a next-level type of care for those patients who meet the criteria? Or do you think that the sponsors, the manufacturers, the pharmaceutical companies want to maintain control of this and develop their own different style of marketing, DTC, if you will, to find and identify the patient that could be appropriate for this and go to them directly? How does the patient actually get hold of the medication and who does that?

Paul Wardle (10:47):
Another great question. Wow! I think I'm going to start with the patient journey. I think on many, many occasions we're used to creating a patient journey to understand where are the barriers, and what are the marketing efforts as a manufacturer of how to reach those patients. And some of them, if they're not getting to the doctor's office, they're outside our audience.

(11:05):
So one reason to think about this is, how do we increase the reach of our medication in new populations? I can see advocacy groups, I can see manufacturers, I can see third parties very interested in, "Hey, there's a mechanism that could increase access for a solution." That, I don't think necessarily belongs with any individual organization. The interest here is, how do you increase public health?

(11:31):
Looking at it from different ways, I think for a manufacturer, there are a number of reasons to think about this. Now, certainly while the life of the brand is patented, if this is a channel, which it can be because it can be executed in parallel to the existing prescription NDA, you could be reaching more consumers sooner and increasing the value of that branded medication far earlier in the life cycle of the medication. So there is a reason to actually think about it as a manufacturer kind of as you're thinking about phase two and phase three trials, "Hey, can we expand the audience for this medication by having a segment of the population that can access it directly?“

(12:07):
Historically, people have often, and we talked about Rx-to-OTC switch last time, they've only thought about that towards the end of the life cycle of a medication. "Hey, it's going off pattern. Hey, can we extend the reach?" That's still a possible reason for thinking about it. But when I look at the US today, most of the medications that are available from prescribers are actually generic. So there are lots of medications where the category itself is generic, and yet there's still unmet need because bringing the price down hasn't changed the access.

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(12:40):
I'll take heart disease for example – whether in cholesterol or hypertension, the number of untreated individuals, is 30 or 40%. We have the medications. The products are available. So it could be a mechanism to increase access to products that are generic today, having a different way of engaging, which is directly with the consumer. And it doesn't replace the existing Rx license. It's actually an additional license, which can be co-marketed at the same time as those other licenses. So it really does open up a door in a different way for access.

(13:12):
Consumer healthcare companies, I think they're going to continue to look at this space. Is it a way to expand usage over the last, I don't know, 20, 30 years? I think there's over 700 medications that were previously prescription that are now non-prescription. It has been a growth driver for consumer healthcare companies. But I think ACNU actually has a far broader audience than typical consumer healthcare. I think it can apply in many other places.

Rusty Ray (13:37):
And how do you see some of the companies that have been around for let's say five to seven years, call it, I don't know, not trying to be flip about this, but they're effectively mail order pharmacies. They advertise on TV. A lot of them seem to be geared towards erectile dysfunction or lifestyle type pharmaceutical products and the like. You still have to qualify, talk to one of their doctors, and you get verified that you are worthy of a prescription. I'd be curious to know how many people they turn down. But then you receive in the mail a discrete brown package with your Viagra or Cialis generic product. Is that pathway that sort of is a commercial pathway that people might look to and say, "Okay, that's how they did it. We might follow suit"? Or do you think that is sort of something that was a bit of an interim step to the true ACNU framework?

Paul Wardle (14:34):
It's a method of access that has been growing for over 10 years now. Certainly it accelerated during COVID when we couldn't get to the doctor. And it does two things. One, it actually says there is consumer interest in this mechanism. Interestingly, that is actually not all governed by the FDA, it's the practice of medicine. So the physician who is actually authorizing that prescription is responsible for it, those systems are evaluated by the FDA in the same way that an ACNU would be.

(15:06):
But there are some key differences. With a prescription product, there are some key differences here from one of these asynchronous telehealth models versus an ACNU. With a prescription product, the manufacturer can't write the prescription. So what you see with those models is they largely supply generic products. And from an industry standpoint, the platforms for dispensing them have become brands. And so there's a number depending on the therapeutic category.

(15:33):
With an ACNU, the sponsor, because the practitioner, the healthcare practitioner, doesn't have to write a prescription for these cases, the manufacturer can actually own the communication to the end consumer. So you can actually see the value of this from a manufacturing standpoint is very different versus those

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telehealth models. And when I look at the value of companies from a profit or sales perspective, direct consumer health companies are valued far greater than either branded pharmaceutical or generic companies. So it is a way of increasing value for a manufacturer by having direct communication. And there's also a value that when you have that communication, you retain that consumer for longer, you create a relationship, but the relationship actually comes with a burden. It's communication.

Rusty Ray (16:17):
That's an interesting comparison. I guess my last question for you today is kind of more along the cost and payer perspective. I'm just kind of curious what your thoughts are on the payer reaction to ACNU in the sense that there's been lots of ink spilled on drug pricing. Medicare's ability to negotiate with manufacturers has been heavily in the news in the recent months. Obviously, we'll see where that lands based on probably the upcoming lawsuits around that. As you think about ACNU, especially with a chronic condition, that's an expensive proposition potentially over the lifetime of a patient, maybe getting a branded product as opposed to a generic or something that's more in the payer or PBM's formulary where they're pushing something that benefits them. So how do payers and the PBM sort of respond to this kind of legislation or regulatory change? And are they seeing it as a good thing or do they see it as a threat?

Paul Wardle (17:13):
That's a complex question, and I'll try and break it down in a couple of ways. I think pricing for a prescription product today is quite complex. It is a cost benefit analysis. So there is the cost of the product. At what level is it reimbursed? What level will the insurance company be willing to pay for it? And you see many situations, I think for ANDAs, less than half of ANDAs that are actually approved ever getting launched because, hey, the commercial valuation wasn't there. There may have been a good consumer reason, but there's not a value seen for actually reimbursing it.

(17:48):
In the same way for an ACNU, and there was actually a public hearing, I want to say around 2013, 2014, where insurers were actually asked to be a part of this process. Now the FDA does not regulate the pricing, but I think the perspective is actually very similar to thinking about pricing on the prescription side. We'll have to do a complex analysis. What is the benefit of covering it for an insurer? And the benefit is more complex if you can avert sequelae from that condition. Let's say you have somebody on a cholesterol medication and they don't have a heart attack, they don't have a stroke, you're averting other costs in the healthcare system. There are cost savings in the system. So you can do a health economic analysis to say, "What is the benefit for the insurance company to cover a particular medication within an ACNU versus not?" And one of the requests that they did have in that prior public hearing was, "Hey, call this something different. So we can actually make that an evaluation of whether or not to cover it."

(18:45):
So I think what we'll see is depending on the condition, depending on the product, we may actually see a number of products actually being covered. And I think this goes back to the unmet need. If in heart disease, which is the leading cause of death in the US, 34 people dying every second, would it benefit us for more people to get the appropriate medication? Yes, I think it would. Would it reduce overall healthcare costs?

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Actually, there's a number of studies that have actually indicated that. So there is a cost benefit for that equation. And actually having direct access reduces a lot of costs in the system. So it doesn't replace the doctor for those that need it, but for some individuals, it may be a more efficient way of getting them coverage.

(19:24):
I think one of the things insurers are going to want to do is know that it's not being diverted for inappropriate reasons. They're actually covering the individual that is covered. So some mechanism that reinforces that. Historically that's been a prescription in order to get non-prescription coverage, but actually we may see now with the advent of technology and solutions, other ways for that to get incorporated as a covered benefit. I think it is something that will evolve, but it will always be a product and situation by situation evaluation. As a result, I think it actually behooves an organization to think about this early in the development because if it's covered and it's still pattern protected, there could be incredible value for increasing the population. And the insurance coverage may not be the issue that we think about historically for non-prescription products.

Rusty Ray (20:13):
How is this different from what we have today?

Paul Wardle (20:15):
How is this different from what we have today. The regulations that govern prescription products and non-prescription products today were governed by the Durham-Humphrey Act in 1951. And essentially, a product should be non-prescription unless the characteristics of the product mean that a physician's intervention is necessary. In reality, almost all, but a handful of products have actually gone prescription before they've ever gone to non-prescription. But what that means is access for a medication is defined for everyone by the drug characteristics. So if there is a particular population that may have zero side effect or may be contraindicated, it may end up being prescription for everyone versus not.

(20:59):
What essentially the ACNU does is starts looking at access to medication by the individual. What are the characteristics of the individual that create a positive benefit-risk arguments such that a subset of individuals may be able to get access without talking to a doctor, whereas others whose burden of disease, comorbidities actually suggest, "Yeah, they really should be in a doctor's office"? So access through ACNU means that you can get access to that medication defined based on your own individual characteristics.

(21:33):
Now, obviously the condition is intended to ensure that there's appropriate access and a sponsor must actually demonstrate that through appropriate behavioral studies and the ACNU must be necessary. So if it can be fully OTC, the FDA aren't going to approve it with an ACNU.

(21:49):
But there's also some very interesting things about this rule, which are very different from typical OTCs or non-prescription. One of them is that the ACNU can coexist with that prescription NDA, whereas with an Rx-to-OTC switch, the Rx product is removed when the OTC becomes available. Here, it's actually increasing a

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channel of access in a different way. The FDA has also indicated that companies can consider this mechanism at any point in the life cycle. It could be at the very initiation of a program. It could be while you're thinking about phase two and phase three programs, that, "Hey, this is an additional way to reach more consumers." And I think it actually could add significant value to the pipeline of products when you consider it in that way, that this isn't an end of life strategy. It's actually potentially a patented life cycle component of drug development.

Rusty Ray (22:43):
How does this benefit the public? From the FDA's perspective, how would they look at it?

Paul Wardle (22:48):
I think when we look at non-prescription access, historically, and you can look at a whole number of case studies, when you reduce barriers for patients or consumers to access, the category utilization on average goes up by about 30%. Because we have behavioral barriers of why we don't go to the doctor. Because we have geographical or physical reasons why we don't get there. When you remove some of those barriers and make it more convenient to get access, the utilization goes up. And that's particularly relevant in chronic conditions where these happen over many years and adherence is poor. So the benefit from a healthcare perspective is getting more people onto the appropriate medication and actually having higher adherence to those medications over time, which is a net result and improves the cost benefit for an insurance company, for an individual and for the population at large.

Rusty Ray (23:40):
This wraps up our insightful conversation with Paul, delving into the transformative potential of ACNU in reshaping drug access models. From recognizing diverse medical needs to navigating the complex landscape of payer responses, we've explored this multifaceted regulatory shift. The unique control at grants manufacturers over prescription and dispensing opens up avenues for enhanced value and communication. As we conclude, we've uncovered the distinctive features of this regulatory framework, paving the way for more individualized approach to medical and medication access.

(24:13):
Thank you again, Paul. And should anyone like to learn more, please visit us at Alantra.com.

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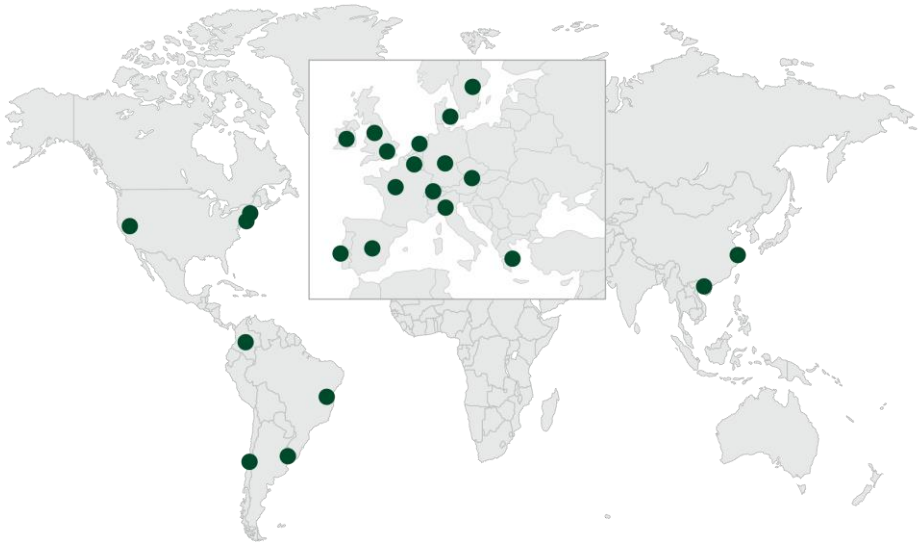

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