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Interview with Cyndy Nayer, Center of Health Engagement

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David Harlow: This is David Harlow at HealthBlawg and I am speaking today with Cyndy Nayer with the Center of Health Engagement. Hi Cyndy, thanks for being with us.

Cyndy Nayer: My pleasure, David. How are you?

David Harlow: Okay. So the Center of Health Engagement is a change agency merging value-based incentives with digital accelerators to achieve health and economic outcomes. One of the fascinating issues that has sort of been on the table these days has been the discussion of a new drug that seems to be doing what it's supposed to do, but it does so at an extremely high cost. I guess that's something that we should talk about: whether the cost of this drug is high relative to what it can do. And I am talking of course about Sovaldi, which is marketed by Gilead Sciences and this is the $1000 a pill drug that is said to cure hepatitis C, previously an intractable disease tied to liver cancer as well.

So, Cyndy, what have you been reading about hepatitis C and Sovaldi? What have you been thinking about the way this new drug works on this disease and what are you thinking about how people can swallow the $1000 a pill cost?

Cyndy Nayer: So the first thing I think we need to put on the table, David, are that the cost are not equal around the world, so let's get that off the table here as quickly as we can. So I've seen numbers of Sovaldi is sold for $57,000 for the full cost of treatment as opposed to the $84,000 in the United States, $57,000 is in the United Kingdom, which means just north of us and just to the west or the east of us across several different ponds you can get it a whole lot cheaper. It is sold for $900 for the total cost of treatment in Egypt.

Now, I don't know what the rationale is for all of that and getting into the politics could become a very hairy discussion. I think what we need to understand here is really what we're solving for? So we have this out of control hepatitis C. It is incredible transmissible. It is a late-stage bloomer, which means that people can be walking around with it for years and years and possibly transmitting it and they don't even know they have it. In the United States alone there are four million folks diagnosed with hepatitis C or hep C as we call it in the lingo and do we know how many more are probably not diagnosed but have it? The estimates that I've seen are anywhere from one to three additional million. So let's focus just if you will on the people that we know are diagnosed with it.

When people are diagnosed with hepatitis C their initial cost of treatment and productivity cost, -- I looked at all of this, people know I have a background in this. I looked at the total economic package of what's the cost of hepatitis C and the reality is that the productivity costs or the absentee costs are not much different many of the other chronic diseases that we seem to live

with, diabetes, heart disease, before they hit the big costs later in life or when they are just completely out of control. So let's take that part off.

Now let's talk about those folks – well first of all we should know that 80% of the four million will develop chronic hepatitis C and it is the chronic hepatitis C that causes these really high escalations in costs and they can be from cirrhosis, which a lot of people know that as an alcoholic's liver, but there are a lot of diseases that affect liver and one of the diseases is cirrhosis. It can develop into hepatic cancer, which is liver cancer and it can lead to transplants. So to be very straightforward what I have done is to look in the literature, in the peer-reviewed journals to see what are the costs of treating all of those. So the total incremental cost of a patient with liver cancer in one year over a patient without liver cancer, just say a normal, everyday person who is not diagnosed with an issue is $43,671. That's in the first year of liver cancer and that's just for the medical cost. Now if we add in the antiviral cost, the drug cost of treating liver cancer at that moment, we add another $145,000, which basically takes this to just under $200,000 for the cost of treating liver cancer.

Now if that person's liver cancer progresses and they need a transplant then the costs go up to roughly a total, including drugs, surgery, inpatient, outpatient care, roughly $670,000 in the first year and then the drugs for antirejection as well as antiviral inflammation can run upwards to $250,000 a year. So when we take a look at a package that says, okay, we can be anywhere from roughly $200,000 with the diagnosis of liver cancer all the way up through $700,000 those are each just one year, $84,000 doesn't seem like a lot of money and I want to be really clear, I am not blowing off that number. It's an extraordinary number. It's just, are we looking at the total costs that could be avoided? -- and that's what I wanted to set up for you.

David Harlow: So that cost of the drug, the course of treatment in the US is $84,000 and as you've described the costs of managing the disease if left uncured through this drug would be many times greater than that.

Cyndy Nayer: Exactly.

David Harlow: I guess the question then arises, has this drug been proven to cure the disease?

Cyndy Nayer: So in the stage 2 and 3 clinical trials, which is what are looked at by the FDA, it has been shown that in a certain group of patients -- which is a large group of patients – it is shown to cure the disease. Now that's a big sentence, because as you know and I know we've seen drugs that have reported to do certain things and 3 to 5 to 10 years later we have found out about side effects that we did not know about when it was okayed by the FDA and in this particular case now CMS, Centers for Medicare & Medicaid, have also agreed to provide this drug for patients who have no other recourse and without it they will die. So that's the requirement under CMS.

But what we don't know is we don't have a long time path. I am sure that the folks at Gilead will say, well yeah, but we studied it for 3 years or 5 years or 20 years, I understand that, but we have all seen drugs that came to market and 5 to 10 years later there were some ungodly side effects that we did not know about and so we haven't had that kind of widespread use yet. On

the other hand, there were headlines just last week that said 9000 people have been cured of hep C and if that's the case that's a pretty big number given what we now know about hepatitis C and how transmissible it is.

David Harlow: So 9000 cases cured -- query how many were on the drug?

Cyndy Nayer: Nine thousand cases cured by Sovaldi.

David Harlow: Understood. Were there 3000 other cases that were not cured, were there 1000 other cases that were not cured?

Cyndy Nayer: That's not out there, we don't know that yet. But it appears that – now there are some other opportunities or other ways the drug is used and for some folks Sovaldi with other antiviral drugs are getting people to goal, but it is taking longer. So all of my data, all of the data that I have published so far has only dealt with, let's assume you are only going to have that seven-week course of treatment, so as an overall number, let's get our hands around it, there are approximately four million people already diagnosed with hep C, 80% of them will develop chronic liver damage and a small percentage of those will develop liver cancer, about anywhere from 1% to 5%, which is about 32,000 people and if we had to treat those people through their lifetime including if they have to go through transplants, it will cost us $360 billion. That's an interesting number to hold in our head as we compare it to $84,000 or even $57,000, which I would argue is still an extraordinarily high cost for a drug. [$84,000 x 32,000 = $2.688 billion]

David Harlow: Right. So is there – you mentioned that CMS was looking at limiting access to certain patients and I know Medicaid programs in different states are looking at the same thing. I guess the question is how stringently should access be limited and is that the only way to move forward given the cost of this drug – since the high cost of the drug has to be paid today whereas the other costs that you are talking about may be paid a year or two from now and we all know that in the political realm that a cost that may show up in two years doesn't carry the same weight as a cost that is going to be incurred this year.

Cyndy Nayer: You're right. You're absolutely right about that. So let me answer that question first. What we don't know once a hep C patient moves into liver damage is exactly how long it will take for that patient to develop liver cancer. We just know if we do nothing they will develop liver cancer. Of course, we have antiretroviral drugs that will forestall the development, but then the question is, well, how much do those cost and honestly I did not – I have some high-level data, but I haven't gone any deeper than that. The concept for me was how do we show that what a value this could be in terms of the lifetime cost of a person who does develop cancer or needs a transplant.

To your question of should we limit access? The FDA approval was for the particular folks who have the genotype, so the DNA genome that matters for Sovaldi. So Sovaldi is best used on those people that have a particular genotype; actually there are four genotypes that they should have. And so FDA says yes, we will – Sovaldi is approved for that. Now there is a study going on right now at Beth Israel in Boston that showed that for those patients who have tried

everything, Sovaldi with another drug, an antiviral drug can actually, according to their study, cure the hep C so that the liver cancer goes away or doesn't come forward.

Under the Affordable Care Act, there is a clause -- and I think you would be the best person to go find it -- it says that no one can be denied care if they have exhausted all the other possibilities or words to that effect and so the big message, the big story was an NPR story about a war veteran, from I believe the Vietnam War, who had developed hep C and who had failed on everything. He was going to die and they made a case to CMS, which caught not only NPR's headlines, but also Kaiser Family Foundation and so there was a lot of publicity that came out that said, okay, CMS has lifted those restrictions and for all of the folks that need to be on this drug -- because nothing else is working we will pay for that. That is a big message to the commercial insurers as well because usually when something passes through Medicare then it translates to some sort of accommodation in the commercial insurance carriers.

David Harlow: Right. Now, the commercial insurance carriers have another issue that they are going to be dealing with because even if we conclude that given the economics and the effectiveness of this drug that it makes sense for Medicare to cover, in the commercial world there is such tremendous turnover from year to year where people switch jobs, other changes in their lives, move from one insurer to another, so an insurer who pays for Sovaldi this year is more than likely not going to be the insurer that "reaps the benefit" of cost savings in future years. So what do you say to commercial insurers who are raising those sorts of questions?

Cyndy Nayer: So there are a bunch of things to say to that. What I am promoting here is this is one of the best scenarios for an outcomes-based contract using value based principles with a three-year contractual arrangement and so, and I'm saying it here first, I'd like to see a three-year contract for Sovaldi in at least the commercial and possibly the governmental sector. Let me give you the background for it, the reason why I've spent so much time on this drug is because I have done work in the HIV community and I remember when HIV was a death sentence and it isn't just much of a death sentence these days, although the treatment can be difficult, but you may remember about a year – actually it was about a year and a half ago, there was a baby that was pronounced cured of HIV because his or her mother took the right drugs when she was pregnant and that was a big headline worldwide, that okay we've got a cure for HIV.

Well, just recently we heard that that baby actually after a year and a half is showing sings of HIV an so for exactly that reason I think with Sovaldi we need to be contracting along those same lines. So let's make it up. Let's say I'm going to use the numbers $57,000 because that's what our UK brethren pay, that's their contract number. So let's say we decide, we can negotiate a price for $57,000 with Gilead and in the first year there are certain metrics that have to be met by everybody. One is the patient is adherent. Two is the providers are doing counseling, the providers defined as health plan and docs and anyone else who surrounds that patient are doing counseling. Three is the patient has to meet certain testing requirements throughout the year, so I believe they're supposed to be tested very couple of months and if the patient does in fact complete all of that and the doctors – whatever the metrics might be and these are very high-level metrics, then that $27,000 is paid to Gilead.

Then in the second year there is coaching that wraps around, there may be financial counseling, there may be emotional counseling, whatever the patient needs, those are guaranteed to be supplied and the person is still covered by the same carrier and the tests, etc., you can see that that would be why the carrier might get involved in this unless there were a group of carriers and then $20,000 will be paid and then in the third year if the test shows that the person is actually still cancer free, the balance of $10,000 would be paid. Now that's a very, very simplistic view of an outcomes-based contract. But it's a way to begin thinking about how do we manage what we know are issues.

The third piece of this is, to your point, there is a new game in town now, which is the ACA, so we don't know how long people will remain with any one carrier, if they will slip, you know, we just rolled it out this year, so we have to get some arms around who bears the brunt if they do change carrier because once you've taken the seven weeks of drugs you can't get it back, so who is going to bear the rest of the cost and that's a discussion that has to come up and frankly I haven't thought that one all the way through yet. I am open to any ideas.

David Harlow: Right. So there is – the question really is can we bifurcate the – can we split the payment from the delivery of the pill, because what we're paying for is not the pills really, what we're paying for is a cure and a cure can only be proven out over time as you described and there are a variety of ways of developing metrics that could be introduced that could help identify has this happened, can it help an individual patient with compliance in other parts of their lives. We talked earlier about some Medicaid programs and others limiting access to the drug, one in particular that I recall reading about was the Illinois Medicaid program, which basically says if a patient has been abusing drugs or alcohol in the prior year then they will not cover Sovaldi. So the support needs to be there post administration of the drug in order to ensure that there aren't relapses of a variety of sorts, so that we're basically giving the patient the best shot possible.

Cyndy Nayer: Exactly.

David Harlow: Have pharmaceutical companies been open to this sort of creative pricing and payment schemes in the past or is this new ground?

Cyndy Nayer: So now this is where it gets really fun for me. So in 2009, I created a slide deck for one of the folks I was working with, one of my colleagues and said we're going into this big summit that we are putting on here, we were part of a national summit, and I've created some slides that showed if we're going to do patient-centered medical homes, if we're going to do patient engagement with value-based benefit design, we need to create a value-based incentive for the delivery system and the reply that I got was I am not comfortable presenting that and I said, well I am, okay, so I'll do it and I did and I stood up in front of nine funders who were pharmaceutical companies and said if we're going to do this, if we're going to do this and everybody were shaking their head yes, so there were about 150 people in that room, oh yeah, that makes sense, yeah, we got to align all the incentives, yeah, yeah, yeah, yeah and I said so the first thing I want to talk about is not contracting for drugs based on rebates. Well, you could have heard a pin drop. But the good news was that within a year I had been asked to come and talk with each of those pharmaceutical companies privately to explain to them what I was doing

and then some of them actually had me come back a couple of times after that as outcomes-based contracts began to move forward.

And that what they found out was the NHS (the "nice" folks in the UK) were already doing an outcomes-based contract with J&J around multiple myeloma and in other words what they were doing is they were putting metrics over time in place and then paying for the drug as the person was adherent and as the results were done and as the different tests were – so I wasn't out there on a limb, although I had no idea that was what was going on. For me it was just how do I equalize the burden here that was what I was thinking when I put the slides together. Well, when I went to talk with some of our health plans who started thinking about this as well and I was talking with a very large health plan, we did road shows together, we did some hard thinking behind closed doors and later WellPoint actually published some data where they had an outcomes-based contract in managing diabetes and hypertension in Cincinnati and the results that they got.

So what they were doing for their outcomes-based contract is they were actually wrapping the pharmacy counselors, pharmacy consulting into the mix and making sure that those people were part of the care team and accelerating the outcomes, getting people adherent, holding them adherent longer over time. But the contact that I have been very vocal about came from Cigna who called me because I had actually been doing some thinking of all of this, as I said, with some of the pharma companies and I can mention this because it is public.

I call it the Cigna-Merck contract and in the Cigna-Merck contract, it was for diabetes and obviously there was a Merck drug, Januvia and Janumet, which are antidiabetic drugs, but there was also things that Cigna had to do in terms of getting the right providers, the right patients screened, etc., they had to accumulate the data, they had to do care coordination because basic care coordination was the best thing that would wrap around, they had to put a value-based benefit design in place, all of those things had to happen and I didn't know that they had actually deployed the contract until they were a year into it and said, we have a year's worth of results and we would like to talk to you and I also had a relationship with Cigna. I did not broker their contract. I had nothing to do with that. I didn't know it was there.

But I have been very vocal about it, because it was not only a rebate-based contract, but the part that everybody has been very quiet about, which was a tremendous game changer was that Merck said to Cigna we will escalate the rebate if people are adherent over time, no matter what drug they are on. Now you never hear a pharmaceutical company saying we are going to escalate a rebate even if you don't use our drug, but Merck wanted to understand what as the proportionality of care, coordination and provider intent and health plan oversight and patient adherence, they wanted to understand what it took to get to goal and goal in this case was adherence over time and lowering the HbA1c. They did it. I am not sure they had a metric on it, they just wanted to see directional movement of lowering and they got it, they got it and so for that reason that's huge.

David Harlow: Right. So we're talking about here is really broadening the playing field to include pharma adherence as part of the mix so that we're ultimately really talking about looking at the potential for bundled payments at the ACO level that could include payment over time for

medications in addition to the payments for physician care, case management, other services along the way.

Cyndy Nayer: And we're talking about chronic disease because we haven't cured diabetes, it makes great sense. I think if we're talking about a very high cost drug I think it still makes great sense even if it purports to cure the disease because we have to give time to play out to see if in fact it really does cure the disease.

David Harlow: Well great. Thank you very much, Cyndy.

Cyndy Nayer: It has been my pleasure.

David Harlow: I've been speaking with Cyndy Nayer about new approaches to contracting for healthcare services and pharmaceuticals. Thank you very much for joining us on HealthBlawg.