STRATEGIC HEALTH CARE

DR. MARK MILLER DISCUSSES FEDERAL PRESCRIPTION DRUG POLICY

Washington, D.C.

Wednesday, November 25, 2020

ANDERSON COURT REPORTING
1800 Diagonal Road, Suite 600
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190

PARTICIPANTS:

Host:

RANDY OOSTRA
President and CEO, ProMedica

Guests:

DAVID INTROCASO, Ph.D.
Vice President, Regulatory Policy
Strategic Health Care

MARK MILLER, PH.D.
Executive Vice President
Arnold Ventures

* * * * *

P R O C E E D I N G S

MR. OOSTRA: Hello. My name is Randy Oostra, President and CEO of ProMedica. I'm pleased to welcome you to this eight-part series of healthcare reform discussions with nationally recognized health policy experts. These interviews will discuss Medicare policy including healthcare pricing, long-term care, and the social determinants of health. This series is part of an ongoing two-year effort by more than a dozen hospital CEOs from around the US to urge Congress to take up significant healthcare policy reform legislation, largely by calling for the creatin of a national commission on healthcare reform.

It is our intent that these policy reforms discussed during these interviews demonstrate our desire for substantive national reform. Moreover, that these interviews help to further inform Congressional members and committee staff as they work to craft legislation to improve healthcare delivery and financing during the next Congress. Our motivation is straightforward.

Well before the onset of the COVID-19 pandemic, we were adamant that race, age and/or economic

circumstances should not be defined as pre-existing conditions nor do we accept the premise that Americans should be resigned to live shorter lives in poorer health. We invite you to listen to or to read the transcripts of all eight interviews. If you'd like to provide comment, you can do so via the content information noted at the conclusion of these interviews.

DR. INTROCASO: Welcome to this series of eight interviews concerning healthcare policy reform. I'm the host, David Introcaso. With me to discuss federal drug policy, moreover prescription drug policy, is Dr. Mark Miller, Executive Vice President at Arnold Ventures and former Executive Director of the Medicare Payment Advisory Commission or MedPAC. Mark, welcome.

DR. MILLER: Thank you for having me.

DR. INTROCASO: Dr. Miller's bio is posted with this interview's audio file and transcript. On background in addition to hospital and physical prices, the topic of my previous interview with Bob Berenson, the US also spends substantially more than comparative countries on prescription medicines.

For example, the US pays three times what the

UK spends for the top 20 highest revenue grossing brand name drugs names and upwards of four times for single source drugs. Medicare Part B and D drugs cost approximately two to four times what comparable countries pay and spending is projected to continue to rise rapidly. High prices are explained largely by economic rent seeking and anti-competitive practices including patent ever-greening and pay for delay tactics.

As a result, medication non-adherence is epidemic, responsible for an estimated 10 percent of hospitalizations. Among Medicare beneficiaries, 90 percent of whom are prescribed medication, upwards of 60 percent are non-adherent in part due to cost. Among those that do adhere, a recent study published in 2018 estimated 42 percent of cancer patients depleted their entire net worth within the first two years of treatment.

So with that as background, let me begin by just asking you generally, Mark, how would you assess US drug pricing policy?

DR. MILLER: I mean I think -- I mean it's a

fairly broad question so we'll see if I'm tracking to what you're asking.

DR. INTROCASO: Just your general overall comments to begin.

DR. MILLER: Yeah. Okay. So then I think I would start here and I would say this. I think the way that I look at this is that in the US, there is something of a, you know, social contract. An innovator comes forward, gets a patent, using that patent and other exclusivities through FDA, is able to market their drug assuming they can bring it to market without competition for an extended period of time.

During that time, I think what the problem has become is more and more launch prices have increased and prices have continued to escalate. Certainly list prices. We can get into net prices if the conversation goes that way. I think the failure in drug pricing is that the same government that grants the patent that gives that manufacturer the opportunity doesn't manage that patent on behalf of consumers and employers which ultimately -- and taxpayers -- which ultimately have to pay for the drug.

DR. INTROCASO: Okay. Thank you. Let's go to unavoidably this conversation or these conversations involve how the US performs or manages these issues relative to comparative countries. So let's go to that. Obviously, the question here is how best to manage drug prices or price growth so let me begin by noting the US has adopted appreciably none, as I'm sure you're well aware, of common pricing policies employed by comparative countries and I'll just name three.

So as you're well aware, among others, comparable countries set or negotiate prices not always by the government. Annual spending increases or annual spending growth, rather, is capped and prices are typically linked to comparative therapeutic value or reimbursement is based on objective standards. So let's start with probably the leading difference between the US and other rich countries and that is the US -- to put it in technical terms -- does not exert it's monopsony power and that is a government either regulating or negotiating prices.

Now, we've seen more discussion about that. This was in, of course, the House bill this past

Congress, HR-3, and the Biden platform included a negotiated pricing provision. So my question for you is will we ever get there relative to some form of regulated or negotiated pricing in the drug space?

DR. MILLER: I mean I think as a country we will eventually get there but I don't think it's going to be anytime soon. I think there is considerable resistance to it. I think in some ways the way it may be ultimately come about is I think as people realize in particular and you've referenced this in some of your opening comments but if a manufacturer has the ability, you know, a monopoly position through the patent and exclusivity laws and regulations, and then generates revenue and then uses that revenue to extend their patent by either keeping competitors off or making very small changes to the product and then shopping the product.

I think at a, you know, a policy that could bring the philosophical differences together is at some point that becomes anti-competitive behavior, that people could agree that extending a patent for 20 years begins to go beyond what the original intent was and so

I could imagine down the road -- not soon but down the road -- where drugs that are expensive and also have had long periods on patent could begin to be pulled into a negotiation process and that would be sort of the way I would guess and that's what I'm doing here that the US could begin to get to a negotiation type of policy. So my answer is yes, but not anytime soon.

DR. INTROCASO: Okay. Thank you. You do know that in the House bill and as a follow up the House bill also included a provision to expand under the Medicare program dental, vision, and hearing reimbursement or services because the House bill was scored at close to 600 trillion -- excuse me -- $600 billion over ten years.

So to what extent do you think that's a sweetener for policymakers because that's a lot of savings that could expand coverage appreciably in the Medicare program?

DR. MILLER: Right. And so in a sense what you're saying in so many words is that drugs will be viewed as an offset.

DR. INTROCASO: Correct.

DR. MILLER: And I absolutely agree that going forward, you know, in the next year -- next two years -- they will be viewed that way in the federal arena and, as you know, and if you know HR-3, HR-3 has three pieces to it. It has the part D reform piece. It has the inflation rebates and then it has the negotiation component and the negotiation component is obviously the biggest component but the Senate bill, you know, Grassley-Widen included two of those pieces which is the Part D reform and the inflation rebate.

So in the short term, I can imagine that and then there is also sets of smaller changes, some related to Medicaid drug policy that those two items and a handful of other items are viewed as offsets in the next Congress or the next Congress and a half, if you will. The next year or next year and a half. And if somebody is trying to, you know, push some kind of initiative forward, whether it's a coverage initiative or, like you said, a benefits expansion or whatever the case may be, drugs will be viewed as an offset.

Now, whether they can get to a negotiation policy that could get through the Congress as I've

suggested I'm more skeptical of that or it would have to be a very skinny negotiation where, you know, a handful of drugs because of their patent exclusivity got pulled into the process but my sense is they work with the other proposals of the next year or year and a half.

DR. INTROCASO: Thank you. I will note as well, and you're well aware of this as the former ED of MedPAC, and that is the projections for the Medicare program solvency in part because of the ongoing pandemic, are getting bleaker and bleaker. Let me ask this as a follow up. I did mention these three of course. The biggest is the monopsony question or negotiation of regulated prices but the other is -- and this gets -- this is really the PCORI (Patient Centered Outcome and Research Institute) question in a sense and that is most other countries or like countries comparable also have some form of -- and the example oftentimes given although the Biden campaign mentioned the German model, but the example I'll oftentimes give is what the UK, the UK's NICE(National Institute for Health and Care Excellence) program which does evaluate the therapeutic as I noted in my question, the

comparative therapeutic value to try to assess the value or worth of a drug.

So this gets the comparative effective research question which PCORI was banned from doing. Will we get there whereby we have some form of entity in the US if nothing else for patient purposes for the consumer purposes, will we have something or might we actually since we do have the Institute for Clinical and Economic Review (ICER), might we give them some authority to do evaluations in therapeutic drugs?

DR. MILLER: Here again I think that there is a -- I think there is a lot of political resistance to that -- that kind of analysis. Arnold Ventures decidedly cares a lot about that kind of analysis and Arnold Ventures supports, you know, ICER for example and its work in looking at drugs for that way. I think that, you know, through the cost effectiveness model. I think that activity will continue. It will be out there.

The industry actually uses it when it's to its advantage it and, you know, criticizes it when it isn't and so as a function it will continue out there. Your

question is more would it really be integrated as part of a policy and I would say only -- and again depending on the time frame we're talking about and I'm talking about the near time, you know, the next couple of years, I think that there is a lot of political -- unfortunately, a lot of political resistance to it so I don't think it becomes a direct measure or a direct mechanism of determining prices.

It could be indirect in the sense that, you know, if for example, there is this kind of skinnied down negotiation that you're potentially talking about, it could be a consideration. Alternatively, to the extent that people are using international prices as refence prices, some of those countries as you've indicated yourself use it in reaching their prices and so it's an indirect measure. I also think the other types of things and you see this in the international pricing that makes it more palatable is rather than fixing it at either a cost effectiveness price or an international price which may include some cost effectiveness, is for the US to add a percentage to it.

So in HR-3, the lane that the negotiation can

occur in is capped at 120 percent of an international price. I think -- so I think where I'm trying to land is to say as a very direct determinant of price again, I think there is a tremendous amount of political resistance to it and that it's either indirect for some years off. The other thing I would say is if you think about it, I think the US and the federal, you know, drug pricing policy process has taken a posture -- I don't know how much this is articulated as much as, you know, just informs the debate that all drugs are available in the US. The question is what to pay for them.

And in the HR-3, a manufacturer, you know, can walk away from the negotiation process. Can, you know, refuse to accept whatever the negotiated price is and still market their drug in this country. What HR-3 does is levies an excise tax for that. And what I think is different about some of the European countries and I believe the UK, the one you've mentioned is the use of the comparative effectiveness is often linked to whether the drug will be offered on the formulary and if the manufacturer refuses the negotiated price, then they are not free to sell the drug at least through their

national health insurance plan. If you see the distinction there. In this country, it doesn't feel like in the policy debate it made a decision or willing to make a decision to take a drug off a formulary.

DR. INTROCASO: Okay. Thank you. Let's stay with the phrase international price. I do have a question also about another aspect of what we see overseas but let's stay with international price because, as you were well aware, last week the administration dropped an interim final rule as a demo for seven years and that's this "most favored nation" termed policy. Much discussion about whether to be legally challenged or not but leaving that aside and of course the Biden campaign also had a similar proposal and that was to reference international pricing. Where do -- where do you see this variation going?

DR. MILLER: Well, I think this variation, you know, using international prices as a reference I think does very much remain part of the legislative and the administrative debate agenda. Whatever word we're using here. And so let me try and go through this in an orderly way. I think that one thing that has had a lot

of impact on people's thinking and by that I mean, you know, citizens broadly is the notion that other countries -- that has really punched through -- that other countries are getting the same drugs and they're paying a lot less and that is a powerful political concern and that, you know, that seems very clear in the public's mind.

So the use of an international reference price plus if you think about it, you know, there is fundamentally three ways to think about the price of a drug. We've discussed one. The cost effectiveness approach. Two, you could sort of try to build a reference point from what, you know, other people are paying for it or even internal to the United States although that’s a lot more complicated for the cost of the drug. Of course, the cost of bringing the drug to market is very opaque and that information is not publicly available.

So I think people gravitate to the international price because it's understandable and it's out there. Now, it does have flaws and can be manipulated but it is out there. Now, as we talked

about just a moment ago, even the HR-3 in the negotiation context, it's governed by 120 percent of the international price. Now, to get to your question on the demonstration of the most favored nations, as a concept, that makes sense and I think that people will continue to consider it.

I mean if the Biden Administration legislatively can't move, you know, changes in drug prices, will be likely I would guess likely to consider administrative paths as well. Now, the proposal that was put out by the administration just recently has some major problems with it. So it would have to be seriously re-thought and re-designed and the major problem with it and, again, I know you know all of this. In Medicare Part B under current law, it works off of an average sales price plus the 6 percent and, you know, where a provider gets reimbursed that regardless of that provider's acquisition costs. So most transactions are covered by the ASP plus six but there are transactions every day in which the provider is taking the drug at a price that is not wholly reimbursed but it is very much, you know, a small percentage of the transactions.

If the international price is implemented without thinking about how the provider gets reimbursed, there could be a major shift in what drugs are purchased by the provider and made available to the Medicare population. So you would have to think about things like whether -- I think it should be checked -- but I think the President's proposal took a lowest price that was out there. You could decidedly have averages.

You could decidedly have averages plus percentages, 120 percent as we've been talking about, to make the price more palatable to the manufacturer and you could also select categories of drugs for example that have greater alternatives such that if a provider was unwilling to take the Medicare price then there would be alternatives and they would lose their market really quickly.

DR. INTROCASO: Yes, thank you. You're right. It's phrase it's the lowest price for the most favored nation.

DR. MILLER: Right. That's what I thought.

DR. INTROCASO: And although it's oftentimes termed the best price and it is a bit of a skinny, to

use your word, proposal in that it would take the best price or lowest of a group of countries for the 50 most expensive drugs bought for Medicare for the Medicare program so it's not an unlimited number.

Per HR-3 just to say per your 120 percent, just to give an example of what these countries are under the HR-3 it was the average price for Australia, Canada, France, Germany, Japan, and the UK and since I mentioned NICE, just to be clear, it's the National Institute for Healthcare Excellence which is the entity that drugs are approved and evaluated in the UK. Let me go to this question. I ask you because I'm genuinely curious. This almost never gets discussed and one of the oddities amongst others relative to the US pricing policy is that other countries when they apply the policy, it applies to all patients and, you know, in the US it's distinctly different.

Its pricing policy is chaotic in the sense that there is pricing policies for some subpopulations, different policies for others. To what extent might we get on the same page relative or comparable to other countries on this issue?

DR. MILLER: Yeah. Okay. Some of that does go on. I think there were active -- and I'm actually embarrassed because I'm forgetting the specifics -- but things like the inflation rebate has decidedly has spillover effects onto the commercial market and, you know, -- but I mean your point stands.

I mean it would provide some indirect effects and there were concerns raised by, you know, some commercial purchasers that, you know, either they didn't want the policy because of a spillover effect or they wanted the policy to apply more broadly. So I think that conversation does get picked up and, unlike some of the other things that I've been saying, is, you know, that have a harder or a less likely path I think those kinds of discussions are being taken up. I mean I should have said this somewhere along the line.

I know it and I know you know it and I know it's quite obvious but most of the time when we're talking about these international comparisons, their insurance system is very different. It is not as fragmented as ours and usually when these decisions are made they apply quite broadly but to try and answer your

question, I do think that there is a very strong interest in keeping the Medicaid reimbursement system somewhat separate with the notion being that, you know, this program is for the poor and that there is some sense that the best rebates and the best prices, you know, literally I know that's a term of art, apply to that particular setting but I think elsewhere in conversations more and more the conversations do encompass commercial and Medicare.

The negotiation in HR-3 applied to both commercial market and to Medicare market and I thought at least in some of the discussions but I don't know that it ever got into law I thought the inflation rebate was also there was some back and forth on whether it would apply more broadly.

DR. INTROCASO: Yes. Thank you. Yes. Your organization, again Arnold Ventures, does a lot of work obviously in the subject and makes any number of policy recommendations. So while you're not as sanguine, appropriately so I imagine, relative to these larger reforms, let me ask about Arnold's policy reform proposals as it relates to drug policy.

You do have specific proposals for Part B and D drugs and then you have some policy proposals relative to and so if you started with the patent issue or the fact that we do not necessarily manage it well, you do have recommendations to curb patent abuses. So feel free to start but I guess on balance what are some of Arnold's more, say, ambitious or substantive policy reform recs here?

DR. MILLER: Well, I think -- I think there are questions and there are policies around product copying. There are policies around citizen petitions. There is policy around, you know, the listing of patents, you know, orange books, purple books. That type of thing. But I think the fundamental objectives that we have around the patent and I would also say drug approval process, the FDA process as distinct from the patent process, our overarching objectives I think are a few things.

One is -- and let me start here. And I know you asked for patent, but let me start here. There is work, you know, that we have going around the FDA where I think there are concerns around the transparency of

information and, you know, at a very fundamental level of making sure that any clinical trial whether it succeeds or fails is publicly available for people to know the results and to learn from and also some of the evidentiary requirements. You know? The use of end point as opposed to actual patient outcomes I think is something that we're concerned about.

And so there are issues around the FDA's transparency and it's evidence process. Another area is biosimilars and in biosimilars the kinds of issues and policies that we're interested in there are, again, evidentiary policy that the standard for getting a biosimilar approved is not so much higher than, say, a reference drug's standard that they have to meet from lot to lot that these drugs are able to come to market more easily and then also to be able to be substituted more directly which is also a function of both federal -- or both FDA approval process and also whether state policy prevents substitution of these drugs. So there's a whole line of kind of work and thinking there.

On patents, I mean I think what it comes down to in terms of our policies and this is very difficult

policy to craft is that what gets patented more truly represents a breakthrough and also what -- how long the patent lasts. And either that the patent terminates or alternatively what we were talking about here. After some date, if there is not a viable competitor which can often be the case, say, in a biologic which the direction that the pipeline is going then, you know, you have to enter into some kind of government negotiation in order to re-negotiate the price which brings us back to our pricing policy. That's kind of a smattering of around the patent and around the FDA process.

DR. INTROCASO: Okay. Thank you. Just to mention quickly since you mentioned ASP, average sales price, you do have a Part B recommendation to reduce or inform the ASP. My final question will be this and I'm genuinely curious again. In my conversation with Bob Berenson, he argued regulating prices can or does drive competition, a position that you're well aware is not widely held but there are those that argue and there is some research out of Europe limiting drug prices through this research creates the same effect, meaning it drives -- can drive competition in that it shifts innovation to

drugs with greater therapeutic value.

So what's your sense relative to this? It would have to be an alternative view, that being that more regulation or regulated pricing does not compromise or subvert competition but actually can drive competition.

DR. MILLER: Yeah. And so I mean I would say a few things. Actually, I might say a little bit about this. You know this all comes from like if you cut $1 then innovation will dry up and, you know, we won't -- we won't have drugs that we want and I want to be really clear. I absolutely believe that there is a relationship between what you pay and innovation and, you know, companies' willingness or investors' willingness to invest in companies.

That said, I think there are a number of reasons on which this, you know, this social compact to kind of go all the way back to the beginning of the conversation in which the government grants the opportunity to make money, to make a drug and to make money without competition and the government's responsibility to make sure that that doesn't get out of

control and hurt consumers and employers and taxpayers. We as a country have to deal with this particular question and I would answer in a couple of ways. I would keep in mind that there is a lot of money in the system.

We're talking about, you know, a $500 billion annual spend here and that there is going to be interest, investor interest, in creating innovations in order to tap into that revenue. So, you know, I think it's important to keep in mind that there is a lot of money and that there is a lot of money that is not currently being directed into R&D. There is work that was done by Peter Bach's group that said the amount of revenue that comes out of the United States alone far exceeds the amount of revenue that is put into R&D worldwide. In other words, you know, there is head room here.

And, you know, the Pharma itself, you know, acknowledges it spends vast amounts of money on advertisement for example. So one thing I would keep in mind here is when, you know, you cut a dollar from a price, there is overhead if you will or sort of head

room if you will and I think people should keep that in mind. I do tend to think that in like -- take a situation like a negotiation or take a situation like another country where they use like, you know, either negotiation or they use comparative or cost effectiveness.

In those countries, when you show up with an innovative drug, you may not get the price that you get in the United States which is top dollar but you get a high price because it's an innovation. If there was some financial pressure put on manufacturers, I do believe that some of what you would lose are drugs that are more like, you know, just to use a term, you know, are more "me too" and more likely creating pressure for the manufacturer to focus on a breakthrough or a drug that has a clear innovation.

I, you know, there is some evidence for that but this is more an opinion than a fact. The other thing I think -- the last two things I would say about this is that, you know, Europe has this other system that uses these negotiation or comparative effectiveness and people often point to it as, you know, that's not

the direction that this country wants to go to but Europe largely has access to the same sets of drugs that we have.

They just pay less for them and they have a more viable biosimilars market than the United States. And so sort of the knee jerk statement that those kinds of methods will stifle and choke off innovation I think are misplaced. The other thing I would say is this and this is the last thing I'll say on this. I'm sorry I'm so --

DR. INTROCASO: No, please.

DR. MILLER: -- long-winded but the other thing I would say is I think we need to have a more intelligent conversation of where innovation is occurring. I mean to the extent it's a small company, single product trying to break through, we may actually want to support a company like that and provide some kind of special support and there are a couple of ways that we could think about that.

I think where the debate has gone wrong is, you know, Pharma has said, you know, we're engaged in innovation. Any dollar taken from us stifles

innovation. Well, that -- you know, large pharma companies are not always where the innovation is occurring. It's often occurring in smaller companies where a pharma is waiting to purchase that company and I think we should be thinking with a more precision about where the innovation is occurring and if we take the dollar from this particular part of the system, we may not be damaging and particularly if we use it to support innovation in another part of the industry, we may not be damaging innovation at all.

DR. INTROCASO: Okay. Thank you. Per your note about US revenue and you cite this in one of your documents and that is the US generated 176 percent of the revenue needed to fund global R&D budgets. So with that, Mark, we're at our time. So I do appreciate this discussion on drug pricing policy. I wish we had time to get at quality and supply issues which are longstanding as well but with that I say thank you again.

DR. MILLER: Okay. Take care of yourself.

* * * * *

CERTIFICATE OF NOTARY PUBLIC

I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Carleton J. Anderson, III

(Signature and Seal on File)

Notary Public in and for the Commonwealth of Virginia

Commission No. 351998

Expires: November 30, 2020