

# **Mackinac Center for Public Policy**

## **Issues and Ideas Forum**

### **“Why Prescription Drugs Are So Expensive and What the State Can Do About It”**

#### **Speakers:**

**Merrill Matthews,**

**Resident Scholar, Institute for Policy Innovation;  
Health Policy Expert and Contributor, Forbes.com;**

**Member, Texas Advisory Committee, U.S. Commission on Civil Rights**

**Peter Pitts,**

**President and Co-Founder, Center for Medicine in the Public Interest;  
Former Associate Commissioner, U.S. Food and Drug Administration**

#### **Introduction and Moderator:**

**Michael Van Beek,**

**Director of Research,  
Mackinac Center for Public Policy**

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MICHAEL VAN BEEK: Good afternoon. We're going to get the program started here. Thank you all for coming. Hope you're enjoying your lunch.

I want to say hi to the crowd that's watching the online stream at Mackinac.org. For those who are attending in person today, just a reminder that this is being recorded. And so if you want to view it later or share it with a friend, you can do that at Mackinac's website.

Welcome to another Issues & Ideas Forum presented by the Mackinac Center. We want to talk a moment and thank Auto-Owners Insurance, who is kind enough to sponsor these events that we host in Lansing on a regular basis.

Before we get started just a couple of things I want to mention. At the end of the presentations, we'll have a period for question and answer. And at your table, there are some cards. If you do have a question, please write it on one of those cards, get the attention of one of my colleagues, and they will bring the card up to the podium for me to read the question. We do that so the audience viewing this online can hear the question and have some idea of what's going on. So that's the way we'll do the Q&A. Also, at the back of the room – there is a table back there with publications from the Mackinac Center that we've published. Feel free to take whatever you like back there, whatever looks interesting. Hopefully, it all looks interesting. But that's available for you as well.

Today's topic is why prescription drugs are so expensive, and what the states can do about it. And we have two excellent presenters to discuss this topic. This is a great opportunity for the Mackinac Center, because this is an area where we don't have a lot of in-house expertise. And so we're very happy to team up with other organizations and other experts who can educate people on these important topics, like this health care issue.

So our presenters are Merrill Matthews and Peter Pitts. Merrill is a resident scholar with the Institute for Policy Innovation. He is a health policy expert and contributor at Forbes.com. He also serves on the Texas Advisory Committee of the U.S. Commission on Civil Rights. Dr. Matthews is a past president of the Health Economics Roundtable for the National Association for Business Economics, the largest trade association of business economists and served for 10 years as the medical ethicist for the University of Texas Southwestern Medical Center's Institutional Review Board for Human Experimentation. That sounds really cool. I want to hear more about that after this, maybe.

Peter Pitts is president and co-founder of the Center for Medicine in the Public Interest. He previously worked for the U.S. Food and Drug Administration as an associate commissioner, policy advisor, and a supervisor of a number of different offices within the FDA. He served on the agency's obesity working group and counterfeit drug taskforce. And he's also authored "Become Strategic or Die," a guide for effective leadership. And he is the editor of the new book called "Coincidence or Crisis," a discussion of global prescription medicine counterfeiting. He has served – he also has served as an adjunct professor at Indiana University's School of Public and Environmental Affairs and also at Butler University.

So please join me in welcoming our two presenters today. (Applause.)

MERRILL MATTHEWS: Thank you, Mike. And we certainly appreciate the Mackinac Center and all the work that they do in the realm of public policy. We're thrilled to be able to be here. You know, I'm from Texas. And anytime between May and August, if you can get up to Michigan, you want to do it. Between December and February, not so much. But we like being able to get out here, and with the nice cooler weather than what we're seeing in Texas right now.

So we're going to be talking a little bit about the growing debate over price transparency in health care, and especially with prescription drugs. But the problem is, price transparency is an issue in the whole health care system, throughout the health care system. It's not just prescription drugs. And especially with the issue of hospitals, price transparency is a real problem. We've seen several stories here recently of somebody who has gone to an emergency room. Wasn't a major issue. Something minor being done. They're there a few hours. Got the bill for that. Might not have had health insurance. Ended up multiple thousands of dollars for that trip to the emergency room.

And the person's saying the news: You know, how can I possibly have spent this much money, and I never knew it until I got the bill afterwards? It is a problem across the country. Prescription drugs make up maybe 10, 12, 14 percent of the total health care spending, depending on how you count. Hospitals make up about 32 percent. Nobody's talking about hospital price transparency. Or, what about insurance price transparency? If you have your health insurance through an employer, I bet you don't know how much your premiums cost. If your employer is paying most or all of the cost, I bet you don't really care how much your premiums cost.

Even people who have gone on the individual market and Obamacare exchanges. If they're getting subsidies from the taxpayers, as about 85 percent do, they may not know what the price of the premium is. And are special subsidies that go behind the scenes that make it even less expensive or less costly for them. People just don't know. Because of that, most people – because of health insurance, most people don't really care what the cost of health care is, which has had an impact on consumers not demanding prices. You know, in almost every other sector of the economy when we go out and we spend our own money, we want to know what it's going to cost. In health care, that hasn't been the case.

And part of it is because of the role of insurance and what's changed. Back in 1960, nearly 50 percent of all health care spending was paid for out of pocket. By 2010, that was about 11 percent of all health care spending paid for out of pocket. People have been increasingly insulated from the price of care, and so they haven't really worried about how much it cost. But that is beginning to change now as health insurance, especially under the Affordable Care Act, is beginning to change the way we interact with the insurance companies and the prices we face.

So insurance has insulated us from the cost. We don't really know how much things are going to cost. But because of the way the Affordable Care Act was structured, insurance companies are increasingly looking for ways to try to keep the premium pressure – the upward

pressure on premiums down. And one of the things they did was they raised deductibles. I mean, in years ago – in years past, if you talked about a \$2,500 deductible, you were talking about a high deductible. People say, nobody can afford that. Now it's common, especially in the bronze plans, \$5,000, \$6,000 deductibles. They did – the insurance companies did that in part to keep their prices down.

But another thing they did is they've increasingly sort of segmented prescription drugs, forcing consumers to pay more out of pocket for it. You know, it used to you had a – if you were buy a generic it was a \$10 copay, if it's a brand name drug it was \$20, maybe \$25. That bumped up. And they said, well, we've got some specialty drugs here. So you got a \$50 copay on this. Then it bumped up to maybe even \$100. Now we've gone to coinsurance, where in many cases if you've got a very expensive drug you're paying 20, 30, 40 percent of the cost of the drug, and the insurance company is paying maybe 60 percent.

And as a result, people are saying: Whoa, what's happening here? Are drugs getting – why are drugs so expensive? Well, drugs have been getting more expensive, at least some of the new ones, for a little while. But there's some reasons for that. And what I'm going to do is show you some of the things that have happened here. The person who tracks – the country's expert on tracking the cost of developing a new drug is a guy name Dr. Joe DiMasi at the Tufts Center in Massachusetts. Joe has been doing this for years. He goes through a very extensive, elaborate process where he tracks drugs that go through the creation process, records the cost of them, factors in a number of things. And he's the go-to person, and has been for several years, about the cost of drugs.

So here's what Joe has come up with. His last one that I've seen, 2016. He looks at direct out-of-pocket cost to create a new drug, about \$1.395 billion; post approval R&D, because once they're approved they're sometimes some follow up work where they look at various things. You put those together, you get about \$1.7 billion for a drug. Now, Joe does something else. He adds in, as an economist, the time value of money. If we invest the money here in a drug, if we invested it in something else we could have made some money here on these investments. So when he adds in that time value of money, he gets up to about \$2.6 billion for a drug. But the direct out-of-pocket costs, about \$1.7 billion.

He gets criticized a lot for that by people who say that's just – that's just not right. That's way too much. It doesn't cost nearly that much to create a new prescription drug. So we – IPI, where I'm from, we don't have the resources to do what Joe does. We don't have the expertise. And so I did something a little easier. I said: You know, there is – we know how much drug companies spend on research and development. It's a published figure. We know how much that is. We know how many drugs are approved every year. And so what I did is I did a comparison on the column there, R&D, billions of dollars spent. As you can see, it's sort of a standard—there's a few dips in it, but for the most part it's an upwardly trending line on R&D spending. You can see in the middle column there how many drugs are approved every year. And then if you do the division there, you get that cost per approved drug.

But because drugs are – some years you have 18 or 20 approved. Another year you'll have 40-45 approved. So it makes it – it makes it really unlevel. So I said, well, what if we just

did this over sort of 10 years – just do a decade of it. So I did the 10-year estimate there, 293 drugs approved over a 10-year period, \$519 billion spent. Comes out to \$1.77 billion. In other words, when you do it this way, it comes out to almost exactly what Joe DiMasi came up with in the same approach.

So this has the benefit of capturing if a drug company went out and said: We're going to – we're going to specialize on trying to find a cure for Alzheimer's, spent several years, several billion dollars trying to do that, but they came to the conclusion it's just not working we're not having any success, that money has to be found – has to be shifted over somewhere. So this ends up catching all of that in the cost of producing a prescription drug. So, Joe's not far off. I mean, there is – it's roughly about that for the direct out-of-pocket cost.

But something's happened with – that's changed here in the last 10 to 15 years with the drug companies. Twenty years ago, they were all oftentimes focusing on drugs that – small-molecule pills that would go out and treat millions of people. Increasingly, they focused on rare diseases – a rare disease is defined as a disease that treats, say, 200,000 people or fewer. And so they've increasingly been focusing on the rare diseases in their research and development, funneling a lot of money into that aspect of it. But the number of patients has decreased significantly.

So you can see here from this graph on FDA orphan drugs – you can see how many – when you get down there towards 2015-2016, how many drugs are working on there. And you see the little line about – of the approvals there. But that's where they've really changed their focus to these rare diseases that will treat cancers, other things, that are small patient populations. But here's the point: If you take that \$1.7 billion, and you're dividing that into 25 million people – which is, I believe, sort of the estimate of how many people took Lipitor – if you've got 25 million patients taking your drug, you can spread out that \$1.7 billion over an awful lot of people. If you've got 2,500 people who are prospects for that drug, it's going to be a much more expensive drug, just because the patient population is much smaller than it was – than they were focusing on 10 or 20 years ago.

So that's having a big impact on some of the cost of some of the new drugs that are coming out, simply because research costs are the same, patient population in most cases much, much smaller. And there's some other factors there as well. We've got an aging population. This is – this is – sort of accounts for the whole health care spending. We've got an aging population. We're going to be spending more on health care, especially on prescription drugs. Medical advancements, the new technology they're able to come out. Some of the new drugs we're coming out are able to target things we never thought we'd be able to treat. And they're having – they're coming up with ways to be able to treat that.

Single source drugs. In many cases, there's no competition out there for various reasons. And so without that competition, you're not going to have the downward pressure on prices that you get when you get – started getting competition. The FDA's trying to address some of that now. Production problems and shortages in a number of places where they've had just problems being able to produce it. This is true with vaccines. They've had some production shortages

there and problems getting the vaccines out. And that's created some shortages. And then others determine the price.

And so I'm going to turn it over to Peter now to talk a bit about that problem.

PETER PITTS: Thanks, Merrill. Thanks, Mike, for the kind invitation to come talk to you guys today. Good afternoon.

I like coming to Lansing when there's no snow on the ground. I also like coming to Lansing because it gives me the opportunity when my wife says: Where you are going? I can go, here. (Laughter.) That's one of my – I lived in Indianapolis for 10 years, so I understand that having people from New York and Washington come here to tell you what to do is kind of annoying. And I'm not here to do that. I'm here just to kind of lay out in front of you some thinking that you need to consider in terms of what is proper for Michigan. And I don't want to get political, but this is a political topic. So just consider me a former federal official here to help. (Laughter.)

Rising health care costs have left us all feeling ripped off, and especially when it comes to drug prices. We hear a lot about it. The president's been talking about it. It's on the news. You talk about it with your friends. And we're hearing a lot about price gouging. And it makes people mad. It makes voters mad. It's a political issue. We have to do something about it. But the soundbite is drugs are too expensive. Why are drugs too expensive? But when people say, my drugs are too expensive – and I suspect that everybody in this room when you hear that from your friends, and your colleagues, and your sons and daughters, what it means is that my copay or my coinsurance or my deductible is too expensive. And that is something entirely different, because drug companies don't set those rates.

So what we're talking about here is an ecosystem. And I think what you heard from the White House press conference is that there are many different players here. And if we're looking for people to blame, we don't solve the problem. It's an ecosystem problem that requires an ecosystem solution. There's a Japanese proverb that says: Don't fix the blame, fix the problem. And that's great from a public policy perspective. From politics, not so much. Finding people to blame in politics, extremely effective.

And the lack of transparency, as Merrill teed-up, is part of the problem. You know, what drives what people pay at the pump, so to speak, at the pharmacy when you go to pick up your drugs? And that's what I want to talk about today. The people that set the copay rates, the deductible rates, the coinsurance rates are insurance companies and PBMs, prescription benefit managers. You hear a lot about this, but here is one thing to consider. A nice thing about facts is that they generally are true. And so as Casey Stengel used to say, you can look it up. The growth in prescription drug copayments has outpaced the rate of prescription drug prices four to one. Isn't that price gouging?

A lot of us think that the increase in out-of-pocket expenses is the result of higher drug costs. It's – that's kind of a commonsense proposition. If my price at the pharmacy is going up, oftentimes quite substantially as Merrill mentioned, it must be because the price of the product

itself is so much higher. And that's not true. And I know it's counterintuitive, so let's talk about that. Why are copays and coinsurance rates going up? Why aren't large discounts generally negotiated by payers 20, 30, 40 sometimes 50 percent, being passed along to the patient, to the voter, to you at the pharmacy? It would make sense then if PBMs are getting these vast discounts that co-payer rates should be going down. They're going up. What's wrong with this picture?

It goes relatively unreported that insurance companies continue to increase your monthly premiums without really explaining why. Or, if they do explain why, they'll go: Drug prices are higher. That falls under the category but of true, but not accurate. And as they say, everything you read in the paper is true, except for those things you know about personally. The insurance industry claims its costs are increasing because prescription drug costs are busting their budgets. But prescription drugs only account for a small part of the monthly premium insurance hikes. From 1998 to 2003 insurance companies increased premiums by an average of \$104.62 per person. During that same period, drug costs rose \$22.48 cents. Let me repeat that: Insurance premiums go up \$104 and change. At that same period, drug prices go up \$22 and change.

But it's true that most Americans with health insurance are spending more drugs. Why? One, because we're taking more of them. And reporters ask me: Why are we taking so many more drugs than we did 50 years ago? I'm like, well, there are more drugs to take. It's not a brain science proposition. Anybody—I have—I take statins for high cholesterol. Anybody else take a statin? Statins are a relatively new invention. It's a blockbuster drug. Everybody takes these. When my dad had heart surgery, they split open his thorax, he has a – it took my dad 3 months to recover from the surgery. I'm sure we all have stories like this. Statins keep people out of the hospital. They're extremely cheap, and very efficient.

But the out-of-pocket costs—you know, our premiums, our copays, our deductibles—are really the only time, as Merrill said, that we actually reach into our wallet to pay for health care. You go to the hospital, they give you a bill but no one really looks at it because you're only paying a small percentage of it, unless, of course, you want television, which is another story. Why are we paying hundreds of dollars for television sets that are already installed in the hospital?

So who should we blame? Should we blame big insurance? Partially, because these large out-of-pocket expenses have a really evil and invisible impact. It really reduces people's desire or ability to take their medicines. This is called non-adherence in the policy biz. And the result of higher copays is that over the last five years, visits to the ER have jumped by 17 percent and hospital stays have risen 10 percent. A new study by the Integrated Benefits Institute shows that when employers shift too much of their health care costs to employees – through higher copays, higher deductibles – the companies lose more than they save through absenteeism and lost productivity. Not surprising when you think about it, but how often do we think about it?

I think that prescription benefit managers and insurance companies are what I call the greedy intermediaries. Are they price gouging or just in business? So let's look at the record. Express Scripts is our nation's largest PBM. They've increased their profits per adjusted prescription – OK, profits per adjusted prescription – by 500 percent since 2003. How's your

IRA doing? And this is important for lots of reasons, not the least of which is that it results in higher premiums, higher coinsurance rates, and drives compliance on medication use down. Noncompliance – I really can't stress this enough – is costing our health care system billions – billions, with a B – every year. Isn't that price gouging? And also, it's price gouging at the expense of patient health.

Now often are we talking about patient health? And I'll come around at the end to the White House blueprint, which is talking about lowering costs for patients rather than how do we reduce costs to the system. They're both important, but, you know, a high-class policy-speak that doesn't result in lower prices at pharmacy is just chatter.

Then there's the prescription shell game. Consider what happened in Minneapolis, where a local pharmacy jacked up the price of a kidney medication more than \$6 a pill, or a cancer center in North Carolina that collected nearly \$4,500 for a colon cancer drug that hospitals typically buy for \$60. Is this price gouging? It's going on everywhere. Everybody's doing it. It's wrong. It has to stop. Unfortunately, since we're talking to legislators here, many state legislators ignore such abuses, preferring to concentrate on an alleged misbehavior or greed by big pharma. It plays well. It's a great soundbite. Nobody questions it. But can we really only blame one part of the health care ecosystem?

Back to PBMs, pharmacy benefit managers administer prescription drug plans for many health insurers and employers. And they've gotten very stingy as of late as to what they choose to reimburse, what they choose to cover, what their formularies look like. As recently as 2012, Express Scripts, the company I mentioned before, largest PBM, excluded no medicines from its list of covered drugs, while CVS Caremark – PBM largest number two – left off about 30 drugs. Today, they exclude more than 200, including an array of popular treatments for arthritis, hepatitis C, and various skin conditions. Another way you drive profits up is by denying care, or by driving patients to the medicines that you want to provide, versus what the doctor thinks is best.

PBMs increasingly refuse to pay for patients' medicines. In 2016, Express Scripts denied coverage to 124 medicines. CVS banished an additional 14. They're not only denying lifesaving medicines, they're driving up health care costs. If you don't give patients the medicines they need, their outcomes don't get better, they end up in the hospital, health care costs go up. Again, this is just math. The numbers support it anyway you choose to look at it. PBMs maintain drug formularies, a list of medication under anybody's particular health plan. When you call up your insurance company and they go, well, that's not covered, that means it's off-formulary in complicated speak.

And their influence—the influence of PBMs is massive, because they cover over 210 million Americans through employers, unions, government programs, and things like Medicare Part D. And they have important roles to play. They do streamline the process. They do have hard negotiating tactics. But consider this: the profits of PBMs largely come from the rebates they get from drug manufacturers. Now, what do they do with those rebates? They pocket them. They get rebates. They pocket them. It doesn't result in a wider, broader, more inclusive



formulary for patients. It doesn't result in lower copays or lower coinsurance. They pocket them.

And I think what's important is what you heard Secretary Azar say the other day at the press conference that the president held at the White House, was that HHS, the Department of Health and Human Services, is going to demand by fiat that at least 30 percent of the rebates that PBMs receive from drug companies for government employees and government plans like Medicare and Medicaid – that 30 percent of those savings be passed down to the consumer in the form of lower copays, lower deductibles, and lower coinsurance. Thirty percent. It doesn't sound like a big ask, but already you can see the lobbyists loading up their weapons for a big fight.

In 2015, a lot of pharmacies sued Express Scripts because they said there was a scheme to deny all claims for certain types of medications. And this is what they said, quote, "The scheme is forcing patients to go without treatment, jeopardizing their health and causing bodily harm, or forcing them to pay out-of-pocket sums, that they may or may not be able to afford, for basic health care needs that have been prescribed by their doctors." That really says it all. Without medicine, patients grow sicker, they require more expensive hospitals and nursing homes. Prescriptions filled and taken are almost always the most cost-effective treatment.

Let me ask you a question. You guys are smart. You support Mackinac – I hope they do. What percent of the U.S. health care spend is on pharmaceuticals? Eleven and a half percent. Yes, well, here's something to do at the Memorial Day barbeque. You ask people: What percent of the U.S. health care dollar is spent on pharmaceuticals? They'll go: 70 cents on the dollar, 50 cents on the dollar, 70 cents on the dollar, 75 – 11.5 cents on the dollar. And for on-patent drugs, the really new ones, the really exciting ones, it's 8.5 percent. Eight-point-five percent. If we stipulated that that 8.5 percent was zeroed out, that all those drugs were going to be free, would our health care system be fixed? Hardly.

It's shameful to withhold medications from sick patients, because it raises the financial burden on everybody else. We cannot let this happen. They're not paying for cutting-edge cancer drugs. They're not paying for cutting edge hepatitis C treatments. Kareem Abdul-Jabbar, for you basketball fans out there, was previously diagnosed with Leukemia nine years ago. He took a drug called Tassigna, and today he's cured and thriving. You know, it's nice to hear that rich people with great health care benefits have access to these medicines. And it's a good anecdote, and he's a good guy. He's got a lot to say. But we can't allow that to be the anecdote. We need to focus on what real people have to deal with every day.

And there's some devious things I really need to point out to you. Merrill mentioned the whole issue of people being denied care, and having to go back and ask again, and again, and again. When you asked your doctor to get prior authorization for a drug, the PBMs charge for that. So when your doctor picks up the phone to call the insurance company to get you authorized to use a more expensive drug, you pay for that too. A lot of games being played. When a doctor switches you from a new drug to an old drug, from a brand name to a generic, they don't always feel that it is their responsibility to inform your physician. Generic drugs are great. They're safe and effective. They lower costs in this country and enormous amount. One of my sons has

epilepsy. When your child is switched from one drug to a generic, the doctor needs to know so that if something goes wrong they know what to look at.

George Paz was the chairman of Express Scripts. And this is what he said on a public earnings call in 2010. I'm not making this up. Quote: "The cheapest drugs is where we make our profits. Our whole model is switching people to lower-cost drugs. The more money my shareholders make, the more money I make." Unquote. Now, I'm a free-market guy. I believe in making money. I believe in the capitalist system. But I believe that if you're in the health care business, you have a higher calling. It's OK to make money. It's good to make money. You have to make money. But you can't put that ahead of your primary mission, which is being in the health care business, which means driving positive patient outcomes whenever and wherever possible.

P.S., according to Salary.com, George Paz made \$14,805,000. And of that, 1,324,000 (dollars) was received as a salary, 3 million (dollars) as a bonus, 3.4 million (dollars) in stock options. Now, what's driving the behavior of corporate integrity? Ten percent – 11.5 percent of our health care spend is on prescription drugs. Why aren't we looking at the bigger picture? As Oscar Wilde said, "The truth is rarely pure, and never simple."

What about price gouging by big pharma? There are problems. A lot of these players do things that we would not do ourselves, that we don't appreciate them doing. But rather than blaming big pharma, or big insurance, or doctors, or pharmacists, or people that don't take their drugs, we all need to be part of the solution. So rather than pointing fingers to score cheap political points, I think that we should all remember that disease is the enemy.

Let me tee-up just a few things that we can discuss relative to the president's announcement the other day. As I said, it was called Blueprint for Patients, not for pharmaceutical companies or for insurance companies, but for patients. How do we lower the price at the pump for patients when they go to the pharmacy to get their drugs? We talked about low – about passing through PBM rebates. That's a start. And then people say, well, if we lower copays at the pharmacy, then the premium rates are going to go up. This is the line you will hear from insurance companies.

But that also points out that the basic – one of the basic design flaws of the Affordable Care Act is that there's a difference between having insurance and having access to health care. You'll read regularly in certain parts of the media: Look at all the many millions of Americans now who have health care who didn't have health care before. But if you have a health care plan for free or at low-cost premiums as Merrill mentioned, but when you go to the pharmacy you have these enormous copays, where is the victory in that? If you go to a pharmacy in many states and your insurance cost for a drug is \$15, but it'll cost you \$10 if you pay cash, in many states the pharmacist is not allowed to tell you that. That's called the gag rule. The president's plan says the gag rule should go away, certainly for any drug that's being dispensed and paid for by the government.

Should Medicare and Medicaid be allowed to negotiate prices directly with pharmaceutical companies? That's a very good debate. That's called the noninterference clause

in policy-speak. Lots of studies by the Congressional Budget Office says that if the government negotiated directly with pharmaceutical companies, they would receive exactly what they're getting now through third-party negotiation. If the government wants to have a shot at it, by all means let them – let them have it, I think, but it's not going to lower drug costs at all.

Now, if you want to really rile up Merrill, ask him about drug importation from Canada. Thank you very much. (Laughter, applause.)

MR. VAN BEEK: Do we have to start there? Do I have to ask you about drug importation from Canada? Do you want to address that? Go for it. (Laughs.)

MR. MATTHEWS: (Laughs.) Actually, Peter knows it better than I do. But there have been several – Vermont just recently passed – it was Vermont, wasn't it?

MR. PITTS: It's on the governor's desk.

MR. MATTHEWS: Yes. Passed legislation, it's on the governor's desk, to allow them to import drugs from Canada. One of the reasons why they passed the – put a prescription drug benefit that they passed in 2003 was to try to address that issue. And then, of course, it's in the Affordable Care Act. But several states, and a few cities, have tried to do this. They – after just a little while, they shut the program down. Nobody used it. It was – it was not effective. Nobody used it. And it was just completely ineffective, I think.

MR. PITTS: And one thing to remember, I think it speaks to the broader issue as well, that 90 percent of the drugs in this country by volume are generic drugs. You ready for this? Write this one down. Generic drugs in the U.S. cost less than generic drugs in Canada. That means 90 percent of the drugs used in this country are less expensive – less expensive – than drugs in Canada. If you have health insurance and you're on an innovator drug, a drug that's on patent with no generic competition, your insurance copay is less than buying it at the counter at a Canadian pharmacy.

And that's if you actually get in your car and drive to a Canadian pharmacy, because most of these plans are about drugs that come to you over the internet or through third parties. They don't lower costs. They are significant safety issues – which people try to pooh-pooh. The state senator in Vermont who started this bill said: Safety is no biggie. Her words. It's a biggie. It's a serious biggie. Minnesota, Illinois, some cities, you know, they put these plans in place, Wisconsin. They've been miserable failures. Nobody uses them. But, you know, it sounds great on television. It sounds like an easy solution to a complex problem. H.L. Mencken said that for every complex there's usually a simple solution that's wrong. And that is one of them. Drug importation falls under that category.

MR. VAN BEEK: We got a few questions coming in. Keep them coming. Keep them coming. I'll ask one of my own to start. So, one of the things that I've heard in the past about – that impacts drug prices is the – is the games that pharmaceutical companies can play to try to prevent generics from getting to market, and thereby allowing their drugs to remain at a high

cost. Can you address that? How big of a factor is that? Is that something that the federal government or states could look at or do something about this?

MR. PITTS: Sure. So this is what FDA Commissioner Scott Gottlieb has dubbed shenanigans. And here's the way that it works. If you're a generic drug company and you want to create a generic drug of the drug that's coming off patent, and to do that you need what's called a reference product. And the reference product is generally the brand. You have to buy that from the manufacturer. So what a lot of manufacturers will do is they'll delay or deny the ability for generic developers to have access to their product.

Today in the news, you'll see that Commissioner Gottlieb has posted a list of companies that have denied their products to generic manufacturers. It's called name and shame, like putting the picture of deadbeat dads in the newspaper. Same proposition. But again, it's complicated. These products have to be shared in a way that is safe and has FDA oversight. And there's some pretty solid legislation pending that, with a little bit of finesse and fixing could help solve this problem. But unfortunately, the tort lawyers are getting involved. And rather than actually trying to fix the problem, they're trying to drive civil penalties that would pad their pockets. So I think that if you take out the focus on suing and penalties, and focus it in one making sure that drug companies can appropriately share their products under FDA supervision, the right thing can get done.

MR. VAN BEEK: I know I don't look it, but I remember a time when there wasn't a drug ad every other commercial on television. What role has that played in – if any – in increased drug costs or increased usage, or that sort of thing, the fact that drug companies now can advertise so widely and all different sorts of mediums.

MR. MATTHEWS: We call that direct to consumer advertising, DTC. I would argue it's actually helped in people getting access to drugs, and perhaps lowering the cost. And I actually – I did a study on this about 15 years ago. And I called some chairman of the marketing departments at a few universities. And I said, check me if I'm wrong on this, but if you're advertising and you're increasing utilization, that allows you to keep prices lower rather than higher. And he said, that's absolutely right. Advertising doesn't increase cost. Advertising actually lowers cost. And the point he made was: If you didn't have – you know the ubiquitous car ads we have out there about buying a car here – car companies aren't required to do that. Do you think you'd be able to get a car cheaper if no car company advertised and you didn't know what was out there or available? It made sense to me.

So that was a while back that we did that study. But I would argue that direct-to-consumer advertising, if it – it both informs patients about things they might not ask about. So after they started doing that, I think you got more patients coming in saying – and, this is, of course, early in the days of the internet when I did this and there wasn't as much information available. But patients started going in and asking doctors about – I saw this ad on this, would this help me? That helped the patient give them more information, but I would argue if it increases sales it actually can lower the cost because you're spreading out that cost among more people.

MR. PITTS: Yeah, well, first of all, as Merrill said, there's no correlation between the amount of advertising a product does and how much it costs, because similar medicines for the same diseases that have different advertising budgets, there's no correlation. Most importantly, however, is that – well, two things. First, doctors don't mis-prescribe because a patient asked for a drug by name. The patient walks into the doctor's office and says: I saw an ad for X, give it to me, if the patient doesn't have the condition the patient doesn't get that drug. So there's no such thing as DTC driving mis-prescribing.

Most importantly, however, is that DTC does drive to a significant degree people to go visit their doctors. And a significant percentage of the doctor visits that are driven by direct to consumer advertising, a previously undiagnosed condition is found and treated. And that is an incredibly important thing to consider, because the way that get people better faster, less expensively, is to diagnose a disease as early in its progression as possible.

MR. VAN BEEK: So, Peter, you talked about kind of the ecosystem here, that we need to look at the whole thing. I was wondering – or, here's a question here about providing more detail perhaps about kind of the typical drug. Who gets paid what? You know, what does a pharmaceutical company get for developing it, what does – how does the insurance company – what do they make off of it. And can you provide – the PBMs, can you provide some kind of typical or general answer about what happens there?

MR. PITTS: No. (Laughter.) I think maybe the best way to – we can have a seminar after the lunch – we can have an eight-hour seminar. Think of it this way. A number of years ago a drug company was asked why it was raising its prices on an insulin product. And they were very honest, they said: Listen, we're raising our prices because the PBMs are demanding higher discounts. We're raising our prices and making less money. So this is all about the ability of the greedy intermediary to suck profits out of the system that somebody has to pay for. And that somebody is the patient.

You know, when you read in the newspaper that a new drug is developed to cure or treat liver cancer, for example. And the company says it's going to cost \$800,000 for the treatment. The number that sticks in your mind is \$800,000. But who pays \$800,000? The answer is nobody, because before the first pill or the first vial leaves the manufacturer's facility, it's already been discounted 30, 40, 50 percent to the insurance company and the prescription benefit manager. During the president's press conference, Secretary Azar said that they were going to consider insisting that drug companies on their direct to consumer ads list – say how much the product – what the list price of the product is. But what's the value in that? Because it's a price nobody pays.

Which comes – I think the question really, Mike, to your point, is transparency. How do we insist that the – that the price of a product, the discounts that are given all on down the line are actually transparent to either the public or, certainly, to a state and federal regulatory authority, so they recognize where profits could be redirected to help patients right now.

MR. MATTHEWS: Let me add something to that, because you talked about sucking profits out of the system. In Medicaid, you have a rebate system there where the drug companies

rebate to the state a certain amount of money for the drugs that they sell. And in many cases, several states have imposed supplemental rebates. So you have a rebate on top of a rebate. But they – if you want – and the compliant by the state is: We need this money to be able to pay more for health care. Drugs are too expensive. We're going to impose a rebate. And we'll get some of that money back.

But think of this – for those of you who are business people, think of this like a tax. If the government comes in and says: You have a business, we're going to impose a tax on you, and you've got higher taxes now, most economists would believe part of that tax may go to lower wages. But it also goes to higher prices, so that the consumers ultimately pay that tax. If you impose a rebate on the companies, they may – you may end up just simply bumping up the price because you're taking money away from them and it drives the price higher, which affects those who are the lowest income worst. So I would argue that the rebates actually – on drugs actually work like a tax and can ultimately drive up the price as well.

MR. PITTS: And another thing about rebates, for those of you involved in state budget scoring, I know in New York Governor Cuomo said, you know, this is how much money we spend on prescription drugs. It's too much. And then somebody said, well, is that number before or after the rebates? And he went, ah, not sure. He went back – the number he had quoted was before rebates. The rebates are a big number. He had to go back and eat crow and completely rescore the budget. So when you're thinking about how much spending on drugs impacts the Michigan state budget, make sure the number you're looking at is the number post-rebate.

MR. VAN BEEK: Question here about biosimilars. What are those? And how might they play into this ecosystem.

MR. PITTS: OK, so this is another five-hour seminar. So a generic drug is – when a small molecule pill, tablet, goes off patent, you get a generic drug. Generic drugs are approved based on bioequivalents, which is an interesting conversation onto itself. When biologics go off patent, they are measured based on similarity, which is a whole other type of measurement, requires clinical studies. And in Europe, bios – the price differ – well, here, the price differential between an on-patent drug and a generic drug can be as much as 85 percent. With biosimilars, at least the European experience has been, that price differential is about 25 to 30 percent, because they're much more expensive to manufacture, requiring clinical trials. It's a different proposition.

Generic drugs are generally what are called AB rated. They're interchangeable. You can take one or the other or the innovator, and it doesn't really make a difference therapeutically – although, there are some differences. With biosimilars in the U.S. right now, there's no such thing as an interchangeable biosimilar. You can't simply switch from one to the other without having significant therapeutic impact, oftentimes negative. The big question is why – for the few biosimilars that are on the market in the U.S. right now – why are the prices almost at the same level as the innovator? Why don't they have a large market share?

And this goes back to the whole issue of pricing transparency, of discounts, of bundling, of kickbacks because, you know, one man's discount and one man's rebate is another man's kickback. So when you make transparent purchasing and negotiation decisions, you understand why consumers really aren't getting as big a bang for their buck as they might at pharmacy or at the hospital or through their insurance programs. And biosimilars ratchets that up, because biologic drugs are much more expensive than small-molecule generics or any type of drug. And they generally treat much more serious conditions.

MR. VAN BEEK: Question here about drug importation again. A couple, actually. So you already mentioned that U.S. consumers might not get as much bang for their buck as what initially they might think.

MR. PITTS: Well, they'll get zero bang for their buck, and there are serious safety problems.

MR. VAN BEEK: OK. So the question is, should they still be allowed to do that if they choose, to import drugs from other companies? And – or, from other countries? And then also a question about – what about prescription drugs in Mexico? Is that – is that another option to provide drugs?

MR. PITTS: Well, let me deal with prescription drugs in Mexico first, which is you've got to be kidding me. (Laughter.) One of the issues with drugs from Canada is that – and I guess it's important to say that the Canadian regulatory system – so, Health Canada is the Canadian version of FDA. They have a world-class operation. You know, if you go to a pharmacy in Toronto or Windsor or anywhere, and you buy a drug at the counter, those drugs are safe and effective. But this is really not about that. This is not about drugs from Canada. This is generally speaking about drugs through Canada. It's an important differentiation.

When we're talking about drugs from Mexico, COFEPRIS is the FDA equivalent in Mexico. And they do as good a job as they possibly can under very significant budgetary constraints. All I would say is it becomes a real caveat emptor proposition. But if people want to drive into Canada, or drive down to Mexico, and buy their products that's called personal importation. And the FDA doesn't have the bang for the buck to stop everybody coming across the border and searching their suitcase and their little amber vials of product. What the FDA does spend its time against is pointing out the dangers of going outside what's called a closed regulatory system. You know, anecdotes don't cut it. The plural of anecdote is not data. And the data that exists relative to drugs coming into this country through the mail, through the internet, is not very good.

MR. MATTHEWS: And I think I'll add – and correct me if I'm wrong on this – it has been legal to import drugs for years, as long as the secretary of HHS is willing to sign off on that, none of them have. Is that correct?

MR. PITTS: Yeah, neither Republican or Democratic Health and Human Services secretaries or FDA commissioners have ever felt that they could say: Yes, it's safe to get drugs from outside of our country.

And the thing about Vermont, for example, is, you know, Vermont, Canada, they're touching. So what's the problem? This isn't about giving the citizens of Vermont an easy pass to drive into Canada. These are – these are internet-based propositions. And the evidence is so profoundly against the safety of this type of situation. And, as it's important to repeat, there no savings. It's people searching for simplistic solutions to complex problems is putting people's lives at risk to score cheap political talking points. Shameful.

MR. VAN BEEK: Question here about the statistic, Peter, that you mentioned about the increased profits for PBMs. Can you talk about – or provide more detail about how that was even possible that they could increase their profits that much, and, you know, do they face any sort of competition that keeps them in check in any way? Or just more detail on that.

MR. PITTS: Well, I guess the question as to how do they do it is they just have – it's intense venal business practices. You know, they're driving to increase their bottom line on the backs of patients. I don't know any other way to put it. Obviously, a chief executive's main job is to watch the stock price. I get it. But these companies have responsibilities as corporate citizens that they're ignoring. How do they get away with it? Their practices are not transparent. Once you sign – once you shine sunlight on these business practices, I would hope they'll be shamed into doing the right thing.

MR. VAN BEEK: So this will be the last question. What can specifically – we talked a lot about increased price transparency, maybe procedural transparency too with PBS and things like that. So what can states do specifically to move that forward for their – for their citizens?

MR. PITTS: Do you want to grapple that one? Well, states are the laboratory of invention. They're the laboratories of invention for welfare reform. We all walked through that a bunch of years ago. They're also the laboratories of invention when it comes to health care reform. And the president and Secretary Azar said they want to give states more authority to pilot innovative programs for exactly these types of propositions.

So I think states, such as Michigan, should step up to the plate and think about ways they could impact greater transparency, lower prices, lower copays for their populations. And talk to people in Washington, put these programs in place, see if they work. Share what they've found with other states. And that's now, I think, we're going to drive good solutions. Not every state is the same. I think what we're going to learn is that what works in Michigan is not going to work in New York. It may work in Arizona but not Idaho. And you have to find the initiatives that work best based on your own individual state circumstances.

MR. MATTHEWS: And one of the things that happen – one of the reasons that PBMs develop is because you've got drug companies that make the drugs over here, you've got buyers out here, pharmacies and so forth. Some of them are small and a lot of time when they first started they were small, independent, family pharmacies and so forth. And so how do you get from here to here in a good, logical method? So PBMs start, negotiate a discount, and they began to create the networks here, because the drug companies don't necessarily want to be



distribution chains to various groups out there, and have the Pfizer truck moving out here and dropping it off at the – at the pharmacy.

So some of these things develop over time, and not with bad intentions. But by the time it develops over time, it becomes a problem. One of the things I believe some companies – some larger companies are beginning to say: Why don't we just bypass the middleman completely and go directly to the pharmaceutical company, and see if we can't get those discounts ourselves, and just bypass that middleman? Because in health care, you've got an awful lot of middlemen. And if you can move some of those middlemen out or reduce their role, you can begin to experience some of the savings yourselves.

I don't know how – you know, Warren Buffett, Amazon, I think, and was it Jamie Dimon, two or three companies said: We're going to look at how we can begin to affect the health care system. They don't know what they're going to do yet. They're just sort of exploring some things. But you get a group that big. And if they can sort of bypass, say, PBMs and get those negotiations directly to – or the discounts directly to theirs, and even make that available through something like Amazon, I think you could see significant discounts going directly to the consumer because you're bypassing an important, costly function in there.

MR. PITTS: You know, any farmers in the room? Caterpillar is using PBMs for only certain types of things. And they're doing it a lot if it themselves. And that has resulted in employees of Caterpillar not having their copays increased for the last 10 years, and having their benefits remain the same. So it can be done. And it doesn't have to be a huge company. Caterpillar's not – it's a big company; it's not a giant company. You know, so smart thinking and focus on the problem can really help to solve the problem.

MR. VAN BEEK: All right. Thank you, Peter and Merrill. Join me in thanking our speakers again. (Applause.) And I thank all of you for attending today. Again, there's publications at the back. Feel free to take whatever looks interesting. This recording will be on the Mackinac Center's website, Mackinac.org.

And just wanted to make you aware of a couple of events that we have coming up. On May 30 we have another Issues & Ideas forum here with – called "Beer Glut: The Overregulation of Alcohol in Michigan." So, again, we'll be talking about a drug, this time a different type of drug. (Laughter.) And then also June 20 we have another Issues & Ideas about technological change and how governments and state governments in particular can help technology flourish. We'll be talking about things like driverless cars and fiber, high-speed internet, and the Internet of Things, and those sorts of issues. So that's on June 20.

So hope to see you there. Thanks again for coming. And have a great rest of your day.

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