

COMMONWEALTH OF PENNSYLVANIA
HOUSE OF REPRESENTATIVES

HEALTH COMMITTEE
PUBLIC HEARING

STATE CAPITOL
HARRISBURG, PA

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TUESDAY, FEBRUARY 25, 2020
9:36 A.M.

PRESENTATION ON
PRESCRIPTION DRUG PRICING

BEFORE:

HONORABLE KATHY L. RAPP, MAJORITY CHAIRWOMAN
HONORABLE VALERIE S. GAYDOS
HONORABLE MARCIA M. HAHN
HONORABLE JOHNATHAN D. HERSHEY
HONORABLE AARON D. KAUFER
HONORABLE DAWN W. KEEFER
HONORABLE CLINT OWLETT
HONORABLE BRAD ROAE
HONORABLE PAUL SCHEMEL
HONORABLE DAVID H. ZIMMERMAN
HONORABLE DAN FRANKEL, DEMOCRATIC CHAIRMAN
HONORABLE MARY JO DALEY
HONORABLE PAMELA A. DELISSIO
HONORABLE ELIZABETH FIEDLER
HONORABLE SARA INNAMORATO
HONORABLE MICHAEL H. SCHLOSSBERG

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*Pennsylvania House of Representatives
Commonwealth of Pennsylvania*

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TESTIFIERS

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SUBMITTED WRITTEN TESTIMONY

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(See submitted written testimony and handouts online.)

P R O C E E D I N G S

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3 MAJORITY CHAIRWOMAN RAPP: Members of the public,
4 thank you for being here today. Due to a lot of concerns
5 that we hear across the Commonwealth from our constituents,
6 this is a hearing in regard to the price of prescription
7 drugs, the cost of those drugs. And obviously, this seems
8 to have drawn a lot of interest from the public.

9 We are in the process of having TV downstairs
10 because I believe it is against regulations to have
11 everybody standing in the hearing room. So, this
12 informational hearing is going to be live-streamed, so
13 we're working on that. Do you know if a video crew has our
14 TVs -- okay. They are setting one up upstairs or
15 downstairs in the lobby. So, if you can find -- there are
16 a couple Chairs right over there. These Chairs here are
17 for our testifiers. But I know security was just here, but
18 there is a problem having everyone standing here.

19 But I'd like to welcome you and thank you for
20 your interest. As I just stated, we know this is a big
21 concern for our constituents across the State of
22 Pennsylvania.

23 I am Representative Kathy Rapp. I am the
24 Chairman of the Health Committee, and I am from Warren
25 County, the 65th Legislative District, and I represent all

1 of Warren County, half of Forest County, and parts of
2 Crawford.

3 And at this time I will have the Members,
4 starting with Chairman Frankel and going to my right,
5 please introduce yourselves.

6 DEMOCRATIC CHAIRMAN FRANKEL: Representative Dan
7 Frankel from Allegheny County, city of Pittsburgh,
8 Democratic Chair of the Health Committee.

9 REPRESENTATIVE ROAE: Representative Brad Roae.
10 I represent most of Crawford County and parts of western
11 Erie County.

12 REPRESENTATIVE HERSHEY: Representative John
13 Hershey from Juniata and Mifflin Counties.

14 REPRESENTATIVE KAUFER: Aaron Kaufer, 120th
15 District, Luzerne County.

16 REPRESENTATIVE HAHN: Marcia Hahn, 138th
17 District, Northampton County.

18 REPRESENTATIVE FIEDLER: Representative Elizabeth
19 Fiedler, south Philadelphia, 184.

20 REPRESENTATIVE SCHLOSSBERG: Good morning.
21 Representative Mike Schlossberg, Lehigh County, city of
22 Allentown, and South Whitehall Township.

23 REPRESENTATIVE OWLETT: Representative Clint
24 Owlett, and I serve in the 68th District, which is all of
25 Tioga County, parts of Bradford, and parts of Potter

1 County.

2 REPRESENTATIVE SCHEMEL: Paul Schemel, I
3 represent a portion of Franklin County.

4 REPRESENTATIVE INNAMORATO: Sara Innamorato, city
5 of Pittsburgh and northern Allegheny County.

6 REPRESENTATIVE DALEY: Good morning. Mary Jo
7 Daley, Montgomery County, collar area of Philadelphia.

8 REPRESENTATIVE DELISSIO: Good morning. Pam
9 DeLissio, I represent the 194th, parts of Philadelphia and
10 Montgomery Counties.

11 MAJORITY CHAIRWOMAN RAPP: Thank you, Members and
12 staff, for being here today for the public's interest.
13 There is also appropriation hearings going on today, so
14 some of our Members, if you see them exit, it is because
15 they also serve on the Appropriations Committee.

16 I would ask you also at this time to please
17 silence your cell phone. This information hearing is being
18 recorded, and it is also, again, being live-streamed.

19 So, at this point I don't want to take any more
20 time away from our testifiers. And our first testifier,
21 welcome, sir. This is Antonio -- I apologize. I'm not
22 going to pronounce your name right. I'll let you --

23 MR. CIACCIA: The last name is Ciaccia.

24 MAJORITY CHAIRWOMAN RAPP: Okay. And you are the
25 CEO of 46 Brooklyn. And so at this point in time are you

1 prepared to go ahead, sir?

2 MR. CIACCIA: Yes, absolutely. I appreciate it
3 very much. Can you all hear me fine?

4 MAJORITY CHAIRWOMAN RAPP: Yes.

5 MR. CIACCIA: Excellent. I apologize I'm not
6 there in person. My wife is due with our third child here
7 in the next week or so, so I was on a no-fly list for this
8 week.

9 It's a treat to speak with you. My entire family
10 is from Pennsylvania, Aliquippa, Beaver County, Centre
11 Township, Monaca, Moon Township, Bensalem, so it's a real
12 treat, so thank you very much.

13 I will get my slides up here. You can see these
14 fine, correct? Excellent.

15 So, my background, just to give you a little bit
16 of an overview, for about a decade I've worked for the Ohio
17 Pharmacists Association. In my time at the Pharmacists
18 Association, I learned that prescription drug pricing is
19 extremely complicated. I still do some work part-time for
20 the Pharmacists Association, so it's an important
21 disclosure there.

22 I'll give you a little bit of a background as to
23 what 46 Brooklyn is and what my consulting firm 3 Axis
24 Advisors is. And it's not a sales pitch by any stretch,
25 but it gives you a good background for why I know what I

1 know and why I know what I don't know.

2 46 Brooklyn Research is a 501(c)(3) nonprofit
3 that we launched in August 2018. Our job is to make drug
4 pricing data more accessible and understandable to the
5 public. In my time working in pharmacy, all I hear about
6 is drug prices are too high, we're spending too much, but I
7 learned very quickly in my time at the Pharmacists
8 Association the nobody knows how prices are set, and nobody
9 understands how essentially those prices end up manifesting
10 their way through the supply chain. So, we try to take
11 publicly available data and create drug pricing
12 visualizations to help other people understand how the
13 system works.

14 We figured that publishing this data would be
15 interesting to maybe nerds and that would be about it.
16 When we launched the website and we started publishing all
17 of our drug pricing chart, we started getting inundated
18 with employers, foundations, researchers who all wanted to
19 use us to help inform their work to try and tame the beast
20 of drug pricing as well. So, we didn't want to do it, but
21 we had a lot of inquiries to do it. So, now our consulting
22 firm 3 Axis Advisors, rather than working with publicly
23 available data, we actually work with plan sponsors,
24 employers, pharmacy groups, benefits consultants, law
25 firms, foundations, and even a Medicare Part D plan to

1 analyze their drug pricing or at least what they're being
2 charged for prescription drug prices.

3 So, my road into this at the Pharmacists
4 Association, I've had pharmacists complaining that they
5 weren't being reimbursed well through the Medicaid Managed
6 Care program any longer. Specifically, overnight
7 pharmacies saw a cut of 60 to 80 percent in their gross
8 margin within the Medicaid Managed Care program in Ohio.
9 Regardless of whether pharmacists get paid enough, too
10 much, too little, doesn't matter. To me, it was very
11 interesting that they saw this massive swing in their
12 reimbursements seemingly overnight.

13 So, I went back to the State of Ohio Medicaid
14 program thinking that I had dropped the ball, and so I
15 asked them if they changed anything. Was there a policy
16 change, or were they just cutting rates? And he said no,
17 they were paying more than they ever had. So, that
18 inspired me to start doing some digging into data that we
19 haven't really looked at before because my frustration with
20 pharmacists was, years ago, when I started doing government
21 affairs for them was that they would walk in with all these
22 screenshots of underpayments from pharmacy benefit managers
23 or PBMs, and they would say, look, you know, I'm not
24 getting paid enough, but, you know, they would give me
25 these receipts and their pharmacy would still be open and

1 they would be losing \$300, \$400 a claim sometimes, at least
2 what they were showing me. And it didn't make sense to me
3 that somehow these businesses were still viable.

4 Well, sure enough, I start asking them questions,
5 and they're making \$300, \$400 on some claims. And since a
6 pharmacy generally needs about \$10 just to break even in
7 margin, a \$300 underpayment and a \$300 overpayment made no
8 sense to me. And so I was very curious how drug prices
9 were being set at that point.

10 So, two years of learning and digging eventually
11 in Ohio led to uncovering hundreds of millions of dollars
12 in the Ohio Medicaid program in hidden drug costs. We
13 essentially were able to discover what's typically referred
14 to as spread pricing where a PBM will pay a pharmacy one
15 rates, and they will bill a different rate back to the plan
16 sponsor, in this case, the Medicaid Managed Care program
17 and the PBM pockets the difference. It's not an inherently
18 wrong thing, but it is an unaccounted-for line item that
19 could add hundreds of millions of dollars into generic drug
20 spending, which we as a society highly rely on in order to
21 balance the books on drug costs.

22 So, we launched 46 Brooklyn to publish and
23 translate publicly available drug pricing to the public,
24 and we launched our consulting firm to help others with
25 their other proprietary data needs.

1 So, just to kind of set the table, the United
2 States spends more on health care than really almost any
3 other country in the world, and we have some of the worst
4 outcomes for it. And so the reason I say this is because
5 typically, in my experience working with members of the
6 drug supply chain, they love to get into aggregate numbers.
7 And on the aggregate, you know, so-and-so is saving money
8 or on the aggregate we're doing great or in the aggregate
9 we're doing poor. Aggregate numbers hide the details of
10 how the sausage is made. And at the highest aggregate
11 level the United States is terrible in terms of health care
12 spending efficiency. And so our job, we feel at least in
13 the drug space, is to help give as much detail as possible
14 to see how the drug expenditures might be contributing to
15 that.

16 So, the first question is are drug costs truly
17 unsustainable? We analyzed drug prices. We use a database
18 called Medi-Span, which is very much the industry standard
19 for tracking drug prices, and those are list prices. And
20 if you're looking at list prices, it seems that while the
21 brand-name drugs are growing and they're rising, they are
22 not rising as much as they used to. That's interesting
23 only because typically, when we talk about the fervor over
24 drug pricing, usually the headlines that you see in the
25 media are about list prices. The problem is is that nobody

1 actually pays list prices. So, what we're seeing in the
2 data is that drug price increases are slowing, but those
3 are list prices.

4 So, what's happening to the net prices? Most
5 people don't know this, but the list price of a
6 prescription drug is typically not what many people
7 actually end up paying. Drug manufacturers, for the
8 purposes of trying to secure positioning on an insurance
9 company or a PBM's formulary, will offer price concessions
10 or what's typically referred to as rebates to offset the
11 cost of the list price of the drug.

12 And what we're seeing is that that rebate or that
13 aggregate amount of discounts that drug makers are giving
14 back to insurers, Medicaid programs, and PBMs, they're
15 growing significantly over time, typically referred to as
16 the gross-to-net bubble. That difference between the list
17 price and what essentially drug makers net out in revenue
18 has actually reached about \$166 billion in 2018. That's
19 the last, you know, large-scale analysis of those rebates.
20 So, when you're talking about drug prices increasing, it's
21 important to track the price, but it's also important to
22 track the other end of the spectrum, which is how much
23 concessions and discounts are being passed back through the
24 system.

25 So, this chart shows essentially how much those

1 increases are occurring over time, so back in 2013 the
2 amount of aggregate rebates and discounts that drug makers
3 offered was \$83 billion, and they have since doubled in
4 2018 to \$166 billion. So, there's a tremendous amount of
5 savings to be had on these prescription drugs, at least
6 brand-name drugs.

7 So, here's a piece from the *Wall Street Journal*
8 that ran just last year where they were analyzing rising
9 prices versus what the actual market clearing rate was, and
10 what they found was that drug prices after the discounts,
11 which, again, are known as rebates, are actually going
12 down.

13 So, in our research we typically refer to rebates
14 as money from sick people. And the reason is is because a
15 lot of people end up being exposed to paying some of the
16 sticker prices on these drugs, but those rebates are
17 garnered by PBMs and insurance companies based on
18 utilization trends. So, the more that a sick consumer
19 enters the marketplace or the more drugs that a sick
20 consumer purchases, if they're getting these high,
21 expensive, brand-name drugs, the more rebates that means
22 for the PBMs and the insurance companies.

23 Now, some of those rebates end up getting passed
24 through and lowering premiums, but not all of those
25 concessions do. So, this is just another way to see that

1 rebates have a significant impact on distorting what the
2 true price of drugs are. And it's true for the commercial
3 sector, it's true for Medicaid, and it's true for Medicare
4 Part D.

5 When you think of rebates, I tell people to think
6 of it as price discrimination, which sounds more insidious
7 than probably people would like, but it's the truth. If
8 the list price of something is \$100, State Medicaid
9 programs, by virtue of mandated discounts, typically will
10 receive the best price. So, what you'll see at the bottom
11 of this, you know, heat chart is that Medicaid programs
12 typically pay the lowest amount off of that list price.
13 And then you have big-four government payers that pay a
14 slightly larger chunk of that price. You have Part D plans
15 that will pay a slightly larger portion of that, and then
16 you'll have large employers that have a much larger
17 exposure to list price. And then you have patients that
18 are in pre-deductible phases. Or when you have small
19 employers that have very little leverage in negotiating
20 power, they typically end up getting exposed to the most of
21 that list price.

22 So, those who understand the game or those who
23 have the most negotiating power, especially governments,
24 they get the most benefit out of those rebates. And so
25 when you think of rebates, think of essentially inequity in

1 payments. I'm not saying it's inherently bad or good. I
2 personally feel that I don't like the way that the system
3 yields winners and losers. But at an aggregate level most
4 people will tell you, well, the drug pricing problem isn't
5 as bad as it used to be or, at a net level, PBMs are
6 controlling costs. Yes, in the aggregate, all of those
7 things could be true, but lost in that aggregate number is
8 the very real side effect that there are winners and losers
9 in terms of who is paying the bill.

10 So, here's just one case study. Advair, it's a
11 very popular inhaler, this was from Axios in April of 2019.
12 One of the largest PBMs in the marketplace, Express
13 Scripts, requires pharmacies to dispense brand-name
14 versions of Advair instead of their generic equivalents.
15 Well, part of the rationale for that is that from Express
16 Scripts' perspective, they get enough rebates in the
17 aggregate for it to essentially make the most dollars and
18 cents for them to grab those rebates, and then they get to
19 determine which plan sponsors will be the beneficiaries of
20 those rebates that they collect.

21 So, Advair could be available at a 70 percent
22 discount, meaning Express Scripts could get a 70 percent
23 rebate from the manufacturer GlaxoSmithKline. It is then
24 up to Express Scripts to decide how much if any of that
25 rebate they want to pass along back to their clients. So,

1 back to the chart that we have showed before, it stands to
2 reason that if Express Scripts is doing this for Medicaid
3 programs, they're likely passing some of those savings
4 through, but for a small employer or a patient in their
5 deductible phase, they're being exposed to more of that
6 list price, essentially not getting that 70 percent
7 discount. And I'm offering that as a hypothetical. I
8 don't have actual data on that in front of me, but I do it
9 for illustrative purposes on how the system works.

10 So, one of our first clients that we did data
11 analytics for was a benefits broker group that does drug
12 pricing research, and they offer expertise to small
13 employers. And what we did is we looked at what was
14 happening to the rebates on the Federal supply schedule.
15 Essentially, the Federal Government, the rebates that they
16 get, we compared them to what the smaller employer group
17 was getting.

18 We found, again, is this massive inequity between
19 the haves and the have-nots. While the Federal supply
20 schedule, if you took their drug utilization and applied it
21 to the rebates that they were getting, it would have been
22 about \$30 million the small employer group would have had
23 if they had the negotiating power and the prowess of the
24 Federal supply schedule.

25 But instead, because they're not in on the game,

1 because they don't have the negotiating power, they only
2 received \$5 million of the rebates that were on the table.
3 So, what's happening is, as those list prices are
4 increasing and the rebates that are being passed through
5 the system are also increasing, the problem of inequity
6 actually gets worse and worse over time for the have-nots.

7 So, the question is, you know, are brand drug
8 costs going up or down? It's very, very complicated.
9 Because all of this data is ultimately proprietary and
10 because it lives below the surface of these aggregate
11 reports, there are people that will come to you as
12 lawmakers and say we're having a hard time controlling our
13 drug spending, but there are others that will not have this
14 problem. And so it's very, very hard to know, because of
15 the discounts that cloud the system, what a fair price for
16 a brand drug is. But that's not necessarily the case for
17 generic drugs.

18 So, here's how the system is supposed to work.
19 We as Americans want new drugs and innovation. Drug
20 patents that we give to manufacturers give them the ability
21 to set prices, and thus, manufacturers have the incentive
22 to bring new drugs into the marketplace. We as Americans
23 grant those manufacturers those patents with a catch, that
24 eventually that patent exclusivity will expire, and when
25 that patent expires, it enables generic manufacturers to

1 enter the market to bring competing versions of the brand
2 drug into the marketplace.

3 By opening the door to new manufacturers,
4 competition should drive prices down, and it typically
5 does. In order for brand manufacturers to create new
6 revenue opportunities for themselves, it's incumbent upon
7 them to bring new drugs to market and replenish the
8 pipeline. So, hopefully, that incentive brings new drugs
9 to market. They lose their patent. In order to make more
10 money they bring others into the marketplace hopefully
11 keeping the churn of innovation.

12 Increasing prices of brand drugs should be offset
13 to a significant degree by the deflation that the generic
14 drug marketplace provides. That's how the system is
15 supposed to work. And here's how it actually works. Many
16 of the new drugs that are brought to market by drug
17 manufacturers are slightly modified versions of old drugs.
18 The drug companies can use rebates to entice PBMs and
19 insurance companies to cover more expensive drugs that have
20 negligible added benefits to the system. Those rebates
21 drive drug companies to raise list prices higher than they
22 otherwise would have without having to give the rebate.
23 And drug makers can use patent thickets that can delay
24 generic competition.

25 After patent exclusivity, the door opens for new

1 manufacturers to enter the market, and they do, and that
2 competition usually does work to drive generic drug prices
3 down. However, most payers are charged rates by insurance
4 companies and PBMs not based on the actual cost of drugs
5 but instead based on unrelated inflated sticker prices.

6 Unfortunately -- and this is what our research
7 bears out in Medicare Part D, in the Medicaid programs, and
8 the commercial sector -- the benefits of generic drug
9 deflation do not end up getting passed in their entirety
10 onto payers, and this has a huge impact on inflating
11 overall drug spending.

12 So, the question is if generic drugs are actually
13 going down in price, why aren't payers or plan sponsors
14 actually being shown those savings? Here's an example in
15 the State of Pennsylvania. So, this is from our 46
16 Brooklyn website where we track national average drug
17 acquisition costs, which are surveyed invoice prices that
18 pharmacies report to CMS on the cost that they pay to
19 acquire their drugs before they get any of their own
20 rebates and concessions from the wholesalers that they
21 purchased them from. That's the blue line. The orange
22 line is a quarterly breakdown of what the Medicaid Managed
23 Care program in the State of Pennsylvania is being
24 essentially charged for those same drugs.

25 This drug is generic Gleevec. It is a leukemia

1 drug. The actual market clearing price of that drug or the
2 NADAC decreased 95 percent from the second quarter of 2016
3 to the second quarter of 2019, so a significant amount of
4 deflation the market was working. However, the rate that
5 the State of Pennsylvania was being charged increased by
6 over 18,000 percent over the same time period. That is the
7 orange line.

8 So, at some point this difference between the
9 orange line and the red line is a shared margin between the
10 pharmacy and the PBM. The only difference between the
11 pharmacy and the PBM is that it's the PBM that gets to set
12 the price of the orange line. So, at some point the markup
13 on that drug was pennies on the dollar. And, over time, it
14 increased to over \$105 per pill.

15 So, this is the data crumb trail that we
16 ultimately followed in the State of Ohio. As pharmacies
17 were complaining that they weren't making enough money in
18 the Medicaid Managed Care program, as I said, on the other
19 end of the spectrum the State Medicaid program was paying
20 more than they ever had. We showed lawmakers and State
21 Auditor Dave Yost all these charts that we showed you
22 before for the State of Ohio, and ultimately, they said
23 there's a problem here.

24 So, the Auditor opened the books and ultimately
25 found that there was a massive gap that was growing over

1 time between the rates of what were actually being paid to
2 pharmacies and then billed back to the States. That audit
3 revealed that \$244 million in spread pricing was being
4 captured by PBMs within the Medicaid Managed Care program
5 over the course of just one year. This amounted to about
6 \$6 per prescription, which, according to the Medicaid
7 analyst who studied this, said it was three to six times
8 the going rate for typical PBM services. So, the cost of
9 generic drugs were in fact going down, but the PBMs and
10 really the drug supply chain as a whole was not passing the
11 savings back on to the State.

12 And the reason this was occurring is because plan
13 sponsors, whether it's Medicaid Managed Care programs,
14 commercial employers, or Medicare Part D plans, are not
15 paying for generic costs based on actual market-clearing
16 rates of those drugs. So, in an inflationary market you
17 want to actually pay based on the real cost of the drug,
18 not an inflated sticker price.

19 What this chart shows you is that the blue line
20 shows what is happening in the aggregate on generic drug
21 prices on a per-unit basis. So, if you took all the
22 generic drugs in the marketplace and threw them into one
23 bucket, what you see in the blue line is that, in the
24 aggregate, generic drug costs are in fact going down over
25 time, but because State Medicaid programs, commercial

1 plans, et cetera, are not paying based on true pricing,
2 they're being charged based on list prices, which is
3 average wholesale price. That's the red line. That's the
4 sticker price.

5 So, while actual drug costs, generic drug costs
6 are going down over time, if you look at the list prices of
7 those same drugs, they're increasing significantly over
8 time. The price that you're being exposed to typically as
9 those that are paying the bill is the red line, not the
10 blue line.

11 So, ultimately, the system is built on what we
12 call bogus pricing benchmarks because they're not
13 reflective of true, actual market-clearing rates. And if
14 you listen to insurance companies and PBMs, they will tell
15 you this in their SEC filings and in their 10Ks. They are
16 completely reliant on average wholesale price as a backbone
17 of their contracts that they have with their payers. This
18 is from Cigna's 10K. Here's one from CVS Health also
19 saying their reliance on average wholesale price to set
20 prices in the marketplace.

21 Because AWP or list prices have little relation
22 to actual drug costs, this is what provides the opportunity
23 for members of the supply chain to capitalize on arbitrage.
24 You have a known price that is not inserted into the
25 equation, and so when the system relies on bogus prices,

1 that's where all the games can be played.

2 So, here's the fallout of using these bogus
3 pricing benchmarks. This is the Medicare Part D program.
4 Every little line on these charts represents what each
5 insurance company or Medicare Part D plan is reporting back
6 to CMS as the cost of a specific drug. This drug on the
7 top is generic Abilify, which is one of the most popular
8 drugs out there. What you see here in very, very small
9 lettering is that the actual NADAC price or the typical
10 pharmacy acquisition price for this drug is 26 cents per
11 pill. What this chart shows is that plans are paying
12 anywhere from that rate all the way up to nearly \$20 per
13 pill. The distribution of the rates that the plans are
14 being charged are all over the map.

15 The chart underneath that is generic Gleevec.
16 Again, that's that leukemia drug I mentioned before. Here
17 the NADAC price or the actual price for pharmacies to
18 acquire the drug is \$14.36. What you see here is that
19 there are plans are paying anywhere from \$12 per pill all
20 the way up to more than \$300 per pill. This is all over
21 the same time period, the first quarter of 2019. That was
22 Medicare Part D.

23 This is the State Medicaid programs. This is
24 vitamin D cream, generic Dovonex. This is a manmade form
25 of vitamin D. What you see here is that the actual NADAC

1 price of this is \$1.57 per unit. That's the cost it takes
2 for pharmacies to acquire the drug. What you see on this
3 map is the different rates that are being charged to
4 Medicaid Managed Care plans in every State across the
5 country. You see a \$1.34 in the State of Iowa. You see
6 \$4.16 in Florida, \$2.49 in Pennsylvania. Pennsylvania is
7 actually getting a relatively speaking better price than
8 other States.

9 What you see here is that over the same time
10 period, this drug is \$1.57 per unit for pharmacies to
11 acquire, and the pharmacies generally get paid very similar
12 rates across the board. But what you see is that the end
13 payer is not getting exposed to anywhere close to that
14 market-clearing rate.

15 Our most recent project that we did is we did a
16 public records request of the State of Florida where they
17 actually gave us claim-level detail of what every pharmacy
18 in the State was essentially being paid on a per-claim
19 basis, so every drug in the marketplace going back to the
20 year 2012 we were able to see what the State was being
21 charged pharmacy by pharmacy, drug by drug, insurance
22 company by insurance company.

23 And this is the exact same drug where the price
24 is just under \$2 per unit, and what you see is one health
25 plan, the price is a buck 51. Another health plan is

1 \$2.72, \$3.19, \$3.89, \$4.44, \$6.58. The gray line here
2 shows the number of prescriptions that were dispensed in
3 this system under this pricing structure. And surprise,
4 surprise, the plan that had the most expensive pricing on
5 this drug saw the most prescriptions dispensed. So, what
6 we believe happened was that PBMs and insurance companies
7 were overpaying pharmacies on these particular drugs, and
8 pharmacies in the State of Florida, seeking margin,
9 actively went out to try and chase as many of those
10 overpriced prescriptions as they can. And so this is the
11 fallout of that.

12 Just to give you an idea of how profitable this
13 vitamin D cream was for pharmacies in the State of Florida,
14 we found one pharmacy called MedZDirect, which dispensed an
15 overwhelmingly disproportionate share of the calcipotriene
16 cream or vitamin D cream in the State. They made \$1.8
17 million alone in one year on the dispensing of generic
18 calcipotriene cream.

19 To give you an idea of how screwed up that is,
20 that margin that this pharmacy made on one drug was
21 equivalent to all the margin that community pharmacies made
22 on all generic drugs for 980 pharmacies. So, 980
23 pharmacies' worth of quote/unquote profit was equal to all
24 the profit that MedZDirect made on just calcipotriene
25 cream.

1 Now, shame on MedZDirect for going out and
2 chasing that margin, but my pushback to lawmakers on this
3 is, look, the pharmacy doesn't create the incentive. The
4 PBM ultimately determines what they will pay from drug to
5 drug to drug. And so the PBM actually chose to set that
6 price absurdly high, which is what we show in the previous
7 chart, and so the pharmacy, seeing where the incentive was,
8 went out and grabbed it. So, when you have pricing
9 benchmarks that aren't based on real prices, this is the
10 fallout. It's not just PBMs that can overcharge you. It's
11 pharmacies who can take advantage of the incentives that
12 PBMs and insurers push into the system to increase the cost
13 for the State.

14 So, here's a breakdown of how this looks with
15 sticker prices on generic drugs. So, the sticker prices,
16 as I mentioned, on generic drugs bear no relation to the
17 actual cost of these drugs. And what each one of these
18 dots represents is what every insurance plan essentially
19 guaranteed as an aggregate discount off of those list
20 prices to a group of commercial payers that we analyzed.
21 What you see again here is that, plan to plan in the
22 commercial sector, the rate that the insurance companies
23 and PBMs are delivering back to commercial payers is all
24 over the map.

25 Here are a few drugs that we picked out that

1 shows you the pricing differentials from plan to plan
2 across all of these commercial payers. So, all of these
3 are the exact same drugs dispensed over the exact same time
4 period. The star equals the NADAC or what the actual price
5 of the drug is, and what you see is that the prices that
6 the payers are being exposed to, they're almost no relation
7 or no consistency whatsoever back to the actual cost of
8 that drug.

9 The same thing is happening in the TRICARE
10 program federally, so for our armed services, prices that
11 are all over the map on a drug-by-drug basis, month-by-
12 month basis.

13 Here is some data from our Florida project that
14 just came out. This is the Centene plan. Centene is a
15 very large Medicaid Managed Care program in the State of
16 Florida and States across the country. What we found here
17 was that Centene signed up for CVS Caremark as their PBM
18 midway through 2017, meaning that CVS Caremark acting as
19 the PBM was able to set prices in the pharmacy marketplace
20 starting midway through 2017. So, Caremark -- most of you
21 know CVS is the pharmacies but don't know Caremark as the
22 PBM.

23 What you see here is that when CVS Caremark got
24 to set prices once they took over PBM services for Centene
25 that all of a sudden the payments on some drugs all of a

1 sudden collapsed for grocery store pharmacies and
2 independent pharmacies, but all of a sudden the rates that
3 were being reported back through the State Medicaid program
4 for CVS pharmacies shot through the roof. So, CVS Caremark
5 got the keys to control where the money goes within the
6 Centene plan in Florida.

7 What we found was that overall in 2018, 94
8 percent of all the margin that was paid out of generic drug
9 claims in the pharmacy marketplace was reported on claims
10 that were dispensed as CVS pharmacies.

11 This drug in this chart is generic Abilify where
12 we show that when CVS Caremark took over acting as the PBM
13 or the price setter for Centene, all of a sudden the rates
14 paid to competing pharmacies to CVS Pharmacy fell through
15 the floor, and the rates that were being reported at CVS
16 Pharmacies skyrocketed.

17 So, back to Ohio, how did we figure out what was
18 going on in this system in the first place? What we found
19 is that the State was paying about 20 percent more per
20 member per month on prescribed drugs within the Medicaid
21 Managed Care program from 2015 to 2017. Now, what's
22 interesting to us because over that time period is when we
23 saw all the margin of attrition occurring at the pharmacy
24 marketplace.

25 We ended up asking for an itemized receipt for a

1 breakdown of where the per-member, per-month rates were
2 being influenced the most, and what we found was that in a
3 period of significant generic drug deflation the State of
4 Ohio actually saw increasing costs on a per-unit basis on
5 generic drugs. That was our canary in the coal mine that
6 perhaps there was being some gaming done on generic drug
7 prices.

8 It was at that moment when I walked through the
9 doors of *The Columbus Dispatch*, shoutout to local
10 journalism. I walked in with our charts and I said, look,
11 I think that there's a problem here. We're seeing issues
12 with underpayments to pharmacies but big-time increases in
13 what the State is investing in the drug spend. I walked
14 out of my first meeting with them, and they said we think
15 that there will be two or three big articles that we can
16 make out of it. They have since written 160 articles,
17 podcasts, letters, and editorials, all dedicated to
18 uncovering what's happening in the prescription drug supply
19 chain and how PBMs set prices in the system.

20 *The Dispatch's* relentless coverage here in Ohio
21 forced the Department of Medicaid to end up performing its
22 own audit. As I mentioned, the State Auditor ended up
23 opening the books to the Medicaid Managed Care program.
24 They found \$244 million of hidden spread pricing revenue
25 that was being pulled out of the system by PBMs. This

1 equated to 31 percent markup on all generic drugs that were
2 dispensed to the Medicaid program.

3 So, since then, this has really kind of
4 snowballed outside of Ohio, so there are States across the
5 country that are now doing their own audits. There are
6 States that are now banning spread pricing. All of those
7 things certainly add clarity into the system, but they
8 don't actually attack the root problem, and that is our
9 reliance on those bogus pricing benchmarks. So, in Ohio
10 they ended up instituting full transparency requirements in
11 the Medicaid Managed Care program, and they banned spread
12 pricing. So, the question is if PBMs were making \$244
13 million off of this line item before, where were they
14 essentially moving to make that money after the fact?

15 So, we did data analytics in Michigan, and they
16 also banned spread pricing in 2018. What we found is that
17 when the State banned spread pricing, all of a sudden
18 payments to pharmacies exploded. We saw huge increases in
19 the rates that were being paid to pharmacies, so the
20 pharmacies were quite happy at first, but then they
21 realized that, rather than the PBM paying the pharmacy one
22 rate and billing a different rate back to the plan sponsor,
23 what they did is they changed their contracts to pay the
24 pharmacy one rate, bill that same rate back to the plan
25 sponsor of the Medicaid program, but then claw back the

1 money after the fact when the money was essentially out of
2 the visibility of the plan sponsor.

3 MAJORITY CHAIRWOMAN RAPP: Antonio, this is --

4 MR. CIACCIA: Yes.

5 MAJORITY CHAIRWOMAN RAPP: -- Chairman Rapp, and
6 we have a couple other speakers that we need to get to.

7 And our next presenter has an appointment that she has to
8 leave I think at 11:00. Can you hang on for questions at
9 the end or do you want to give us a --

10 MR. CIACCIA: I would be more than happy to do
11 so, yes.

12 MAJORITY CHAIRWOMAN RAPP: Okay. Thank you so
13 much. Then we'll get back to you.

14 MR. CIACCIA: Okay, great.

15 MAJORITY CHAIRWOMAN RAPP: And very interesting.
16 Thank you so very much. And if you can hold on for
17 questions at the end, we'd love to hear more from you.

18 MR. CIACCIA: You got it.

19 MAJORITY CHAIRWOMAN RAPP: Very interesting.
20 Thank you. Thank you for all the handouts.

21 So, our next presenters -- and before I introduce
22 Janet Horvath -- Janet, just hold on for a second -- I'd
23 like to recognize Representative Dawn Keefer and
24 Representative Dave Zimmerman. Anybody else that came in
25 during introductions? Okay.

1 So, our next presenter is Jane Horvath. Jane,
2 thank you for being here. Jane is the Senior Policy Fellow
3 at the National Academy for the State Health Policy. And,
4 Janet, whenever you're ready, please proceed.

5 MS. HORVATH: So, thank you very much for the
6 opportunity to be here today, Chairwoman and Chairman. I
7 actually don't work at the National Academy for State
8 Health Policy. I left there in 2018, and I have foundation
9 funding and other support to work with States and advocacy
10 organizations on prescription drug cost policy. Okay. So,
11 I apologize for that error.

12 I think what I'm going to do is set my testimony
13 aside other than to make a couple points about it and then
14 zero in on a lot of what we heard this morning and thinking
15 about it as policymakers if that's okay and then you can
16 get back on track.

17 But I did want to say that, first off, nobody's
18 walking with God in this industry. I mean, you know, it is
19 just a highly dysfunctional marketplace on so many levels,
20 as we've just heard. And I'm not going to repeat any of
21 that. But there are deep, deep problems. There are deep,
22 deep problems in the generic industry, and those are
23 separate from the deep, deep problems of the brand
24 industry. And, again, there's enough going on to point
25 fingers every which way, which is the problem for

1 policymakers.

2 And, as State policymakers in particular, you
3 know, I've worked with a number of States now in a
4 different capacity than Anthony, but back of the envelope,
5 most States, their tax revenues support the pharmacy
6 benefits or support the pharmacy services of about 25
7 percent of the State population, so that's a huge stake of
8 State residents and you as policymakers responsible for the
9 fisc of the State. You know, that's Medicaid, that's
10 prisons, that's university employees and retirees, State
11 employees and retirees. It just goes down the list. And
12 I'm sure Pennsylvania is probably right in that main.

13 So, I have spent a good deal of time, over a
14 decade, in the brand industry itself. I worked for Merck
15 and did some consulting for biopharma, and I've always been
16 concerned about prices. And it's become clear to me that
17 even the players that want to do different, they can't do
18 different. They can't step out. And so there's a role for
19 public policy in this space.

20 I also think that the problems start with high
21 prices, and I understand why, as Anthony has said, why
22 prices are getting higher and higher, the gross-to-net
23 bubble. That is all very real. But all of this started
24 with high prices and sort of all the machinations that have
25 built up around manufacturer high pricing to try to deal

1 with it. And I'd say it's all a little out of control at
2 this point from soup to nuts.

3 And there's reasons why manufacturers want to
4 maintain their ability to price, you know, have just sort
5 of unfettered ability to price, which is what they do in
6 the U.S. market today. I think they need a high U.S. price
7 for purposes of international reference pricing, which many
8 other countries do. And they also just -- you know, no
9 industry likes to have their ability to set their prices
10 regulated.

11 But I will say that the traditional role of
12 States has been protecting the health, safety, and welfare
13 of their residents. And States have stepped in since the
14 early 1900s to regulate industries with high dysfunction or
15 the potential for high dysfunction when there is the
16 opportunity for monopoly pricing and where State resident
17 health and safety is at risk. And I think that this is
18 similar here.

19 And I think one of the ways to think about this
20 is for State policymakers to consider ways of creating
21 transparency in the whole supply chain starting with the
22 price that the manufacturers set and then making sure that
23 there is absolute transparency throughout the whole thing
24 so that some of these machinations that we see can't
25 happen.

1 And in my testimony I do talk about a
2 prescription drug affordability board. I've talked about
3 all different ways that States are trying to create
4 transparency and manage the problem here. But in my years
5 I really think that the solution at least at the State
6 level until we can get some good Federal action going here
7 would be a prescription board of a certain -- you know, you
8 can set it up different ways, but it totally mirrors what
9 States have done for 120 years now on public utilities.

10 And once what the consumer will pay is
11 established, then everything else falls in line. And, you
12 know, you don't have the profit-taking on the drugs from
13 the insurance industry or the PBMs or the pharmacies. It's
14 also a way -- one of the key pieces of dysfunction in this
15 market is that everybody makes money off of the price. I
16 mean, that's how it's done, and that's why, you know, we
17 get to this situation.

18 Even back to academic research institutions who
19 do the bench science, the lab coat science that develops
20 the molecule that looks like it might help somebody, then
21 they license it, they patent it, the academic institutions,
22 and then they'll sell it to Pfizer or Merck and they'll
23 collect royalties on it. And so they, even going all the
24 way back there, have an interest in high drug prices, you
25 know. And the wholesaler has an interest in high drug

1 prices, but I think less. They make their money more on
2 sort of volume.

3 The PBMs, the health insurance are just trying to
4 stay afloat by getting these rebates and trying to keep
5 premiums down. That's a really important thing, and the
6 health insurance industry, as you know, making premiums
7 affordable so that your risk pool is stable and all of
8 that, so all rebates don't go to consumers. They do go to
9 premium stabilization.

10 What else did I want to say here? Oh, you know,
11 just -- so I also think that we're seeing a huge problem
12 with launch prices. You know, launch prices of new drugs,
13 new, really important drugs are going up and up and up.
14 There seems to be no limits on the ability of
15 manufacturers. We have chronic disease meds that people
16 who are going to take them for the rest of their lives,
17 they start out at \$300,000 or \$400,000 a year, you know,
18 and they're not necessarily tiny populations. And so,
19 again, we really have to think about this in a
20 comprehensive manner because there is just these systemic
21 problems.

22 Anyway, I guess that's really the guts of what I
23 wanted to say. And one more thing was that I think, as
24 policymakers, you need to focus on affordability and not
25 product value because that's what's missing here in this

1 discussion is what's affordable. What's affordable for the
2 patients, Medicaid program, insurers, State employees.
3 What's affordable? And affordable means what's affordable
4 so that every patient who needs that drug, you know, is
5 indicated for that drug can get that drug, which would
6 ultimately mean more sales for manufacturers than they get
7 now because their drugs are so high-priced. Everybody who
8 needs the drug doesn't get it, so sort of, you know, more
9 affordable cost and more utilization and more transparency.
10 And I would say leave the value equation to clinicians and
11 doctors.

12 That's really it.

13 MAJORITY CHAIRWOMAN RAPP: Thank you very much.

14 I understand that you do have to leave shortly. Could you
15 take a few questions?

16 MS. HORVATH: Yes, I have to catch a plane. I
17 have to leave here, end of time 11 o'clock, so --

18 MAJORITY CHAIRWOMAN RAPP: And we're time-
19 constrained, too.

20 MS. HORVATH: I know. I know.

21 MAJORITY CHAIRWOMAN RAPP: Chairman Frankel, did
22 you have anything?

23 DEMOCRATIC CHAIRMAN FRANKEL: Yes. First of all,
24 thank you, Jane. I've had the opportunity to meet with you
25 on a number of occasions, and the concept of a

1 pharmaceutical affordability board is something that I've
2 been exploring and have introduced legislation with respect
3 to.

4 Let me ask you, first of all, maybe you can give
5 us a quick rundown. I mean, one of the key items that I
6 take from the legislation that's modeled after your model
7 that is now in place in Maryland is this issue of almost
8 like a Public Utility Commission --

9 MS. HORVATH: Right.

10 DEMOCRATIC CHAIRMAN FRANKEL: -- and setting
11 prices. So, as I understand it -- and I'd like you to
12 maybe to go through this briefly. You know, instead of
13 having all these different layers adding to the price where
14 everybody gets a piece of the pie, the pharmaceutical
15 affordability board basically sets the price, and then you
16 work down from there as to where everybody is getting their
17 slice. Maybe you can kind of detail that a little bit.

18 MS. HORVATH: Yes. And I will say I did develop
19 the model and trying to think about like how to manage this
20 and how to manage it fairly because I have great respect
21 for the drug industry. I think it's terrible that people
22 so despise the industry because of pricing and that people
23 can't get their meds. I mean, that's not why these
24 companies exist. That's not why scientists work for these
25 companies.

1 So, a drug affordability board, you know, I think
2 in this day and age if it were to be created tomorrow would
3 consult with health plans and State payers and everybody
4 else and figure out what is their net. What is that gross-
5 to-net bubble there? And in some cases it's 70 or 80
6 percent. And maybe that then becomes the upper payment
7 limit in a State. That becomes what consumers pay. That
8 becomes what every transaction around the State is, is
9 built on what the consumer pays.

10 And manufacturers aren't necessarily taking a hit
11 at that point if they're already giving at the office 70
12 percent off in terms of rebates to somebody in the system.
13 It's just taking that and making it the number and building
14 the whole supply chain off of it.

15 And the most important thing in terms of making
16 things affordable is to make sure that the pharmacy pays an
17 affordable cost and that the pharmacy bills the insurer and
18 the patient that affordable cost. Like nothing's going to
19 change as long as everything is rebates and confidential
20 and stuff. And, you know, pharma is right that, you know,
21 they're giving a massive amount in terms of rebates. And
22 if that money just sort of moved up front, it would benefit
23 the patients. So much more would change as a result of
24 that.

25 And I'm just saying you could do that off the

1 top. That may still not be an affordable drug, but there's
2 just that much money in the system now to even just start
3 to work with.

4 DEMOCRATIC CHAIRMAN FRANKEL: Thank you. And one
5 other quick item, maybe not quick, but can you tell us what
6 percentage of a drug's cost is research and development or
7 manufacturing and how much of drug costs are manufacturers
8 spending on advertising and administration and how much is
9 profit roughly since you've been in the industry?

10 MS. HORVATH: No, I can't. Those are
11 confidential numbers, and the company I work for knew
12 better than to tell me those things. I mean, if that's not
13 your business in the company, you know, you don't
14 necessarily know, and those are numbers that the industry
15 finds to be trade secrets.

16 And I guess my feeling is at the point in time in
17 which it becomes important for the industry to tell you
18 that for purposes of policymaking, they will. And if it's
19 really not germane, they won't. But if it's not germane to
20 them, it shouldn't be germane to policymakers. That's the
21 view I've come to.

22 DEMOCRATIC CHAIRMAN FRANKEL: Thank you.

23 MAJORITY CHAIRWOMAN RAPP: Thank you, Chairman
24 Frankel. Representative DeLissio has a question.

25 REPRESENTATIVE DELISSIO: Yes, thank you,

1 Chairwoman.

2 When you had commented, Ms. Horvath, that rebates
3 go to insurers for premium stabilization, I might be more
4 inclined to embrace that if so many of the executives and
5 insurance companies weren't making seven-figure salaries.
6 So, I'd be curious to see -- because we see this even in
7 the utility companies as to how this -- and I think
8 absolutely something needs to be done, but how this
9 regulatory process even currently as it pertains to
10 utilities, you know, the rates still go up, I still have
11 constituents who pay more for the very basics, which are
12 heat, electric, water. And for many of them there are
13 still budget strains --

14 MS. HORVATH: Right.

15 REPRESENTATIVE DELISSIO: -- so I would hope in
16 this case that if we were to head down that road, we would
17 put the appropriate boundaries and restraints in place that
18 doesn't stifle research and development, absolutely
19 important, but what the first speaker was saying and talked
20 about, new drugs were slightly modified versions of an
21 older drug to really keep that market going.

22 MS. HORVATH: Right.

23 REPRESENTATIVE DELISSIO: We're incentivizing I
24 think here the whole wrong thing.

25 MS. HORVATH: Yes.

1 REPRESENTATIVE DELISSIO: This is an enriching
2 folks at the expense of others. When I have somebody
3 saying they have a \$700 copay, that's beyond nuts, and I
4 have to make three phone calls including to the
5 pharmaceutical company in order to get that changed.
6 Nobody should have to go through that.

7 So, as much as I like the concept of some type of
8 a statewide board looking at this, I would just caution my
9 colleagues that we're going to have to be really, really
10 thoughtful because our everyday citizens are not
11 influencing the process as many other special interest
12 groups are. Thank you.

13 MS. HORVATH: I would be the first to say that
14 this idea, it's not perfect. It's not perfect. But I
15 would also anticipate that, as part of this process, you
16 know, health plans need to make some agreements, too, you
17 know, in terms of how they structure it, make some
18 agreements, too, to be part of the process that, you know,
19 once a drug is acted on by the board, yes, you know, it has
20 to be affordable to the patients and then to the health
21 system. And right now, patients are in between everybody.
22 You know, everybody uses the patient to try to leverage
23 their ability to either maintain price or lower price.

24 MAJORITY CHAIRWOMAN RAPP: Thank you.
25 Representative Daley?

1 REPRESENTATIVE DALEY: Thanks, Madam Chair.

2 I was reading to get ready for this meeting, and
3 there was a part of me that was, you know, replacing this
4 whole drug industry and the patient, and it occurred to me
5 that you should handle it like Public Utility Commission in
6 some way.

7 But I also come from a background of working at
8 University of Pennsylvania for 20 years with people who did
9 biomedical research, and so the research aspect of it is
10 interesting and kind of -- well, let's say it's interesting
11 to me because, you know, you see how long it takes for
12 research and all the different phases research goes
13 through, and I think that it's a valuable part of it. And
14 I don't even -- like so many drug companies have shut down
15 their research and development --

16 MS. HORVATH: They have.

17 REPRESENTATIVE DALEY: -- so it's really -- I
18 agree with my colleague, Representative DeLissio, that it
19 was really distressing. And we've heard this before, that
20 there's just a reformulation, slight change to a drug so
21 that the patent period can be extended and then, therefore,
22 the exclusivity. So, you know, is that research part of it
23 also something that we need to be looking at? Because --

24 MS. HORVATH: So --

25 REPRESENTATIVE DALEY: -- it's important, and

1 there are so many things that we're not even addressing in
2 terms of developing treatments for them. I don't know
3 where the money comes from for that. I mean, I don't even
4 know how much the Federal Government puts into it, but
5 that's an area that I think also needs to be explored.

6 MS. HORVATH: So, there's a Federal bill called
7 the We PAID Act, and it also establishes a national
8 prescription drug affordability board basically, but it
9 also looks at that piece. So when a university goes to
10 patent a molecule, in order to get that patent, they've got
11 to report where they got the money from. And if it was a
12 bunch of NIH money -- because everybody feels like we've
13 already paid for the drug in terms of the development and
14 stuff, so as taxpayers and patients, we keep paying and
15 paying and paying. So, I mean, that would be interesting
16 to have disclosure, not that it would crimp academic
17 ability to get NIH funds and use them in research in any
18 way. It just is transparency.

19 And then in terms of the me-too product to sort
20 of extend a patent life, you know what, I think a board
21 could look at that, you know, and decide that, you know,
22 what makes that affordable? Or maybe the board doesn't
23 even need to look at that. Do you know what I mean? Like
24 it's not creating a financial challenge. All of this
25 depends on the drug I think, you know, how many competitor

1 products that do similar things there are in the
2 marketplace so there's not going to be one rule of thumb
3 that it would happen exactly this way. It just depends on
4 the products.

5 REPRESENTATIVE DALEY: That's really interesting.
6 I don't think the Federal Government pays for all of the
7 drugs or the research. I just --

8 MS. HORVATH: No, they don't.

9 REPRESENTATIVE DALEY: I think a fair look at how
10 the research industry in the United States works is also
11 something because it's not really as simple. It's
12 expensive to do research.

13 MS. HORVATH: It is.

14 REPRESENTATIVE DALEY: It's a very competitive
15 area, and you want to keep attracting people to be able to
16 do that kind of work because otherwise, how are we going to
17 make discoveries --

18 MS. HORVATH: Yes.

19 REPRESENTATIVE DALEY: -- so I do appreciate what
20 you're saying. For me, it's raised a lot more questions,
21 which is always a good thing --

22 MS. HORVATH: Yes.

23 REPRESENTATIVE DALEY: -- in public policy.

24 MAJORITY CHAIRWOMAN RAPP: Thank you,
25 Representative. Representative Schlossberg.

1 REPRESENTATIVE SCHLOSSBERG: Thank you. Thank
2 you. And thank you, Ms. Horvath. This has been genuinely
3 interesting.

4 I really appreciate the brief that you laid out
5 for us because I think it does an excellent job of laying
6 out options but also limitations. And it's those
7 limitations that I have some questions on. It seems like
8 everything -- not everything but many of the things that
9 you suggested are limited by case law or FDA law or
10 Medicaid law. Every one of us gets questions about
11 prescription drug prices, and typically, my response -- I
12 suspect the response of many of my colleagues -- is at the
13 State there's not a ton we can do. Within the scope of
14 what you laid out here, what are some options that don't
15 run afoul of any of the pretty significant constraints that
16 we have on us?

17 MS. HORVATH: So, interestingly, importation from
18 Canada seems to be immune from suit, pharmaceutical
19 companies suing the State. And that's what I look at like,
20 you know, who's going to sue? I think PBM disclosure when
21 it's written through the State commercial insurance code as
22 opposed to creating a new section of law for PBMs --

23 REPRESENTATIVE SCHLOSSBERG: We did that if I'm
24 not -- well --

25 MS. HORVATH: You may have. I apologize.

1 REPRESENTATIVE SCHLOSSBERG: No, no, no --

2 MS. HORVATH: But that is an area I think it's
3 going to be hard to sue. And, as we heard, I think some
4 rules around fair business practices in the PBM industry
5 are warranted. And then, again, I apologize. I feel like
6 I'm pitching this thing, and I don't really mean to be
7 doing that, but the board idea is designed -- I mean, it's
8 a little complicated, but it is designed to sustain, be
9 sustained in a dormant commerce clause constitutional
10 challenge. That's why it's based on costs --

11 REPRESENTATIVE SCHLOSSBERG: Right.

12 MS. HORVATH: -- and that upper payment or cost
13 limit is applied to State-licensed and regulated entities.

14 REPRESENTATIVE SCHLOSSBERG: Okay.

15 MS. HORVATH: So, it leaves the manufacturer free
16 to price however they want, wherever they want as opposed
17 to -- so that gets at some of the case law.

18 REPRESENTATIVE SCHLOSSBERG: Right.

19 MS. HORVATH: And then, you know, that board,
20 like importation, it applies to stuff that is --
21 pharmaceuticals in the State intended for patients and
22 individuals in the State. That's another key component.
23 Those are like the pieces. It's got to be in the State,
24 right? It can't be exerting burdensome influence on the
25 behavior of manufacturers outside of the State. It can't

1 violate patent law, so those are really the parameters.

2 REPRESENTATIVE SCHLOSSBERG: So, I have no doubt
3 an accurate answer and a frustrating one because what we
4 can do remains pretty limited it sounds like.

5 MS. HORVATH: It does, and I don't mean to be
6 Debbie Downer, but I do think there are some things --

7 REPRESENTATIVE SCHLOSSBERG: Yes.

8 MS. HORVATH: -- that can be done, and I think
9 the most important thing is setting precedents and having
10 Congress -- because really, you know, the best solution is
11 a national one in this particular arena -- setting
12 precedent and giving them sort of some ideas on where to
13 go. There are two bills now in Congress both on the Senate
14 side on creating a drug affordability board.

15 REPRESENTATIVE SCHLOSSBERG: Thank you very much.

16 MAJORITY CHAIRWOMAN RAPP: Thank you,
17 Representative.

18 I have just a brief question. Where we are
19 seeing a few States in the Nation looking at insulin cap
20 legislation.

21 MS. HORVATH: Yes.

22 MAJORITY CHAIRWOMAN RAPP: Are you familiar with
23 that and --

24 MS. HORVATH: I am.

25 MAJORITY CHAIRWOMAN RAPP: And what's your

1 opinion? And is this something that you believe would be
2 beneficial to people with diabetes?

3 MS. HORVATH: Oh, yes. Yes, absolutely. People
4 are literally dying because they can't afford their
5 insulin, you know, and that's just a horrible situation.
6 So, you know, I think that this is solving for a specific
7 problem. Colorado was the first State, and there's a whole
8 bunch of States now that are requiring their insurers to
9 cap the cost of out-of-pocket cost of insulin. Some States
10 are going further and capping the out-of-pocket cost of all
11 drugs covered by all commercial plans in the State. At a
12 certain point you start to affect the health plan's ability
13 to manage their costs and keep control of their premiums.

14 I don't know -- the industry here should speak to
15 whether a cap based on the health profile of
16 Pennsylvanians, you know, if that is going to be a real
17 problem or not. It wasn't a problem in terms of premiums
18 and all that in Colorado.

19 MAJORITY CHAIRWOMAN RAPP: Thank you very much
20 for being here today. We really --

21 MS. HORVATH: My pleasure.

22 MAJORITY CHAIRWOMAN RAPP: -- appreciate you
23 taking the time out of your busy schedule. Safe travels.
24 Thank you very much, Ms. Horvath.

25 Our next person to present to us today is Sarah

1 Emond, who is the Chief Operating Officer for the Institute
2 for Clinical and Economic Review. You're the Executive
3 Vice President. So, please begin whenever you're ready.

4 MS. EMOND: Well, thank you, Madam Chairwoman,
5 Mr. Chairman, and all of the Honorable Members of the
6 Health Committee, an honor to be with you today. As the
7 Chairwoman noted, I'm from a group called the Institute for
8 Clinical and Economic Review, and that's a mouthful so we
9 can use ICER today as we're talking. And, importantly, I
10 do want to note we do not lobby for any particular pieces
11 of legislation, but we do welcome the opportunity to speak
12 with policymakers about the issues around drug pricing in
13 particular because of where we sit, what we've learned from
14 our research and some of the ideas we have for solutions.

15 We heard a lot today. Antonio did a great job.
16 Jane's done a great job talking about the problem. I'll
17 mention that when we've talked to many manufacturers about
18 how they set their price, we get a lot of different
19 answers. It can be the value that patients receive. It
20 could be the value to society. Some say it's what the
21 market will bear. Others will say it's because of the size
22 of the population that might be treated with the drug.
23 Some say it depends on what our competitors charge. And
24 some even say they have a moral requirement to charge as
25 much as possible.

1 What you hear through all these reasons is
2 inconsistency. There is not one way that a manufacturer
3 chooses its price. They have admitted this, and there's a
4 ton of research that sort of supports the fact that there's
5 no one way. And what that leads to is a situation where
6 those of us who want patients to be able to get access to
7 the drugs that they need, we have no way of judging their
8 choice of price as fair or not fair.

9 And I will reiterate something Antonio mentioned
10 to us earlier. The government is granting a monopoly in
11 this case and allows them the ability to set the price.
12 And so it leads to the question of how do we judge whether
13 or not that price is fair? I don't need to tell Members of
14 this Committee because I've already heard and I could have
15 guessed that you're hearing daily from your constituents
16 about how difficult it is to afford their prescription
17 drugs. Kaiser Family Foundation did a survey back in
18 November that showed 79 percent of respondents said the
19 price of drugs was unreasonable.

20 Drug makers also have no regulatory or statutory
21 restraint on raising prices. Some companies raise prices
22 multiple times a year often at rates much above that of
23 inflation simply, seemingly, because they can. In our
24 first annual unsupported price increase report, we actually
25 found that net price increases on just seven drugs in 2017

1 and 2018 resulted in an excess of \$4.8 billion of spend by
2 Americans.

3 One quick detour into rebates because you're
4 going to hear a lot about rebates. We already have, the
5 gross-to-net bubble, all of these things are very
6 important. I do want to emphasize that this issue is
7 extremely important in a select number of classes of drugs,
8 when there are multiple competitors, when there is the
9 ability for the pharmacy benefit manager to use market
10 forces to extract larger and larger discounts in exchange
11 for formulary placement. And there's times when it harms
12 patients. The idea that patients should be asked to pay a
13 coinsurance on list price when no one is paying list price
14 is frankly bananas, and that's a technical term.

15 And we have little transparency about how the
16 rebate savings are being shared with the payers, with the
17 employers, and with the patients themselves. I'm happy to
18 report that because of the attention that this has
19 received, more and more payers are offering what they call
20 point-of-sale rebates where the patient is paying their
21 coinsurance on net price. This is a step in the right
22 direction but, again, still a symptom of the larger
23 problem.

24 What you have here are both sides pointing
25 fingers, but we believe it is possible to have fair prices,

1 have fair access for patients, and plenty of money for
2 future innovation. We consider this the grand bargain. We
3 think there is a way to incentivize manufacturers through
4 their research and development through the data that they
5 produce to demonstrate the value of their product, and we
6 can reward them with high prices. And what that means is
7 when there's me-too innovation or a drug that only offers a
8 marginal benefit to patients, we don't see quite as high
9 prices.

10 So, how do we do this? Simply, we take the
11 evidence on the clinical benefit -- this evidence comes
12 from the manufacturers themselves as part of the clinical
13 trials for the product -- we calculate a fair price using a
14 systematic review of the drug's comparative clinical
15 effectiveness versus what we already do, combined with an
16 analysis of the drug's long-term cost effectiveness versus
17 the other options.

18 Our methods are transparent. It is an eight-
19 month process. It involves several points for public
20 comment and interaction with patients and their families at
21 the center of the process from day one. Our work aims to
22 signal what a fair price is, not to signal whether or not a
23 patient should be able to get access to that drug.

24 So, a quick primer on cost-effectiveness in 90
25 seconds. Cost-effectiveness measures all of the health

1 gains and the side effects offered by two or more different
2 treatments compared to all of the new costs and the cost
3 savings offered by the therapies. Simply put, cost-
4 effectiveness measures the improvements in length of life
5 and quality of life as judged by the patients taking the
6 medicine often through a measure called the quality
7 adjusted life year, and then we scale the price to the
8 benefits demonstrated by the drug using a consistent and
9 well-established approach linked to the overall wealth of a
10 society.

11 When we conduct cost-effectiveness, we're able to
12 judge the fairness of an estimated net price, which can
13 help signal to policymakers where more attention might be
14 needed. It is possible to have a health system where the
15 prices of drugs are aligned with their health benefit, and
16 we see promising examples of just that.

17 One example was a drug called dupilumab, a new
18 therapy for severe eczema manufactured by Regeneron in
19 Santa Fe. During our review, we were working with the
20 manufacturer because we wanted to be sure we had all of the
21 data available in order to show the full value of this drug
22 and what it meant to patients. And they did just that.
23 They give us access to data that hadn't been published
24 previously. They worked with us to help us understand what
25 the data were showing, the data directly from the patients

1 in their clinical trial, and they made a public commitment
2 to pricing their drug in ICER's fair price range, and in
3 turn then put pressure on payers to make sure that patients
4 got access and that they didn't have to go through onerous
5 utilization management and step therapy. And that's
6 exactly what happened.

7 We have a few other examples that I can get into
8 in the Q&A, but we think that this is the future of how
9 drug pricing can work for patients.

10 I want to note that the work we do is not without
11 controversy. There are many people who have invested in
12 the status quo staying exactly the way it is. And,
13 unfortunately, they have used misinformation and fear to
14 scare patients into thinking that doing cost-effectiveness
15 and measuring improvements in quality of life and length of
16 life somehow discriminates against people with disabilities
17 or those who are older.

18 Measuring the benefits of patients using cost-
19 effectiveness is never used to say that patients that start
20 out healthier should get medicine before patients that are
21 older, sicker, or have disabilities. That would be
22 unethical. The quality adjusted life year is a measure
23 that helps society know the fair price for all patients
24 that took the drug regardless of age, other conditions, or
25 any disabilities those patients have. It would be

1 unethical to try and decide a fair price for the drugs for
2 just people without disabilities or just for young people.

3 We're willing to stand by our work by working
4 with States, Federal policymakers, and others to enact
5 safeguard language that would prevent our work from ever
6 being used to discriminate. This language could say, when
7 using cost-effectiveness, policymakers cannot use
8 information that uses the cost per quality adjusted life
9 year or similar measure to identify subpopulations for
10 which treatment would be less cost-effective due to
11 severity of illness, age, or pre-existing disability.

12 All right. Let's talk about what States can do.
13 Jane did a wonderful job outlining some of the limitations
14 to what States can do but the opportunities that States
15 have to use information to try to get fairer drug prices.
16 I want to tell you what New York did in their Medicaid
17 department. They passed a law in 2017 that put their
18 prescription drug spending for Medicaid on a cap. They
19 used actuarial analyses to say this is how much more we are
20 allowed to spend on prescription drugs year-over-year, and
21 when we are projected to pierce that cap, we are allowed to
22 go look at the drugs, the spending on which is contributing
23 to us overspending on prescription drugs. The legislation
24 gave them a number of tools to extract additional rebates
25 from the manufacturers for the drugs that they've

1 identified.

2 In the first year alone they identified 30 drugs
3 from 12 manufacturers, and they didn't say this publicly,
4 but you can figure it out from math that they got
5 additional rebates on 29 drugs from 11 manufacturers. How
6 we know that math is there was one manufacturer that
7 refused to give a supplemental rebate. That manufacturer
8 is Vertex, and the drug is Orkambi for cystic fibrosis.

9 So, because they refused to give an additional
10 rebate, the law allowed that company to be referred to a
11 public process where the drug utilization review board then
12 looked at information about the utilization of the drug,
13 the price of the drug, how much spending the State has made
14 for the drug. And the drug utilization review board took
15 that information and then said this is a supplemental
16 rebate amount we should get for this drug. An important
17 component of their deliberation was our independent
18 analysis of what a fair price was for Orkambi, which
19 represented a 75 percent discount off of the list price of
20 the drug.

21 ICER's work also informs a pay-up-to approach.
22 We're very happy about the interest we're receiving from
23 policymakers in this approach because this results in broad
24 access for patients. If the ICER price is the ceiling
25 price, you as a payer -- well, Medicaid's a little bit

1 different, but as a payer or some like the VA could say I
2 will pay up to this amount and ensure that all of my
3 members, all of my patients get access, and then we can
4 talk about what we do with the difference. Do you give it
5 to me as a rebate? Is it an up-front discount? Do you use
6 your patient assistance program to help patients afford the
7 difference?

8 There's important nuances that we need to unpack
9 in terms of what you do with that difference, but the idea
10 is getting a lot of traction. It also could play into a
11 prescription drug affordability board. If the prescription
12 drug affordability board is looking for an independent
13 analysis of what the ceiling price should be, something
14 like an ICER report that has a price that shows you the
15 exact price that matches the clinical benefit that a
16 patient receives could be very helpful.

17 The other thing I'll mention is price increases.
18 I mentioned our unsupported price increase report. ICER
19 comes at this by thinking that there are times when a price
20 increase is warranted, and there are people who might
21 disagree with that. But we believe that it would be
22 warranted if the manufacturer approved additional clinical
23 benefit or improved safety. That's exactly what we want to
24 see in postmarketing trials and real-world evidence. If
25 that happened, ICER's research would then show we should be

1 paying a higher price.

2 And our unsupported price increase report
3 identifies drugs that have not demonstrated any additional
4 evidence of value for patients, and so, again, could signal
5 to policymakers here are the drugs that we need to pay
6 attention to in terms of what we need to be thinking about
7 in terms of intervention.

8 I want to just remind everybody -- I don't really
9 need to remind anyone here, I realize that, but, at the end
10 of the day, why are we having this conversation? Why was
11 this room packed this morning? It's because of patients
12 like Ray. Ray saw a drug approved for his rare disease.
13 It was available for \$450,000 a year. Even with insurance,
14 he was facing an unmanageable expense, and Ray knew that
15 his small employer would be facing difficult trade-offs
16 around wages, expansion, and premium increases if he were
17 to take the drug. So, he was deciding whether to take the
18 drug or enter palliative care to preserve some financial
19 resources for his family after he was gone. This is not a
20 decision any of us would ever want to have to make and yet
21 families face in this country every day. We can do better.
22 We can have amazing innovation that improves the lives of
23 patients like Ray without bankrupting families, employers,
24 and States.

25 Again, my thanks for the invitation to be here

1 today. I'd be happy to take any questions.

2 MAJORITY CHAIRWOMAN RAPP: Sarah, if you wouldn't
3 mind, we're going to wait until the next presenter, and
4 then you can come back up and --

5 MS. EMOND: Beautiful.

6 MAJORITY CHAIRWOMAN RAPP: -- we'll ask questions
7 and try to link back up with Antonio as well.

8 So, just for the Members' information, our last
9 presenter that's on the agenda, Christopher Molineaux,
10 actually came down with a bad case of the flu, so he will
11 not be presenting today.

12 So, our next presenter is Lauren Neves, who is
13 the Senior Director of Policy and Research, Pharmaceutical
14 Research and Manufacturers of America. Lauren, welcome,
15 and you may begin whenever you are ready.

16 MS. NEVES: Thank you so much, Chairwoman Rapp,
17 and Members of the Committee. My name, as she just said,
18 is Lauren Neves, and I'm here on behalf of the
19 Pharmaceutical Researchers and Manufacturers of America. I
20 am thrilled to be back in my home State of Pennsylvania,
21 just 30 minutes from where I grew up in Manchester Township
22 in York County, talking about drug prices -- closer? Okay.
23 -- and how we can work together to make sure patients can
24 actually afford their medicines. I think that's something
25 everyone who's spoken here today can agree on.

1 So, my organization, Pharma, represents the
2 country's leading biopharmaceutical companies, and we're
3 devoted to developing treatments that will help patients
4 live longer and better lives. In this decade our member
5 companies have actually invested more than \$900 billion in
6 research for new treatments and cures.

7 And I want to go back to something Jane spoke to
8 earlier. She talked about how we don't talk about what we
9 spend on R&D and what we spend on marketing. That's not
10 true. We are happy to talk about that. In 2016 we spent
11 \$90 billion on R&D, and we spent a third of that on
12 marketing, so I just wanted to go back and correct the
13 record there.

14 America leads the world in medical innovation
15 driven by a market-based health care system and policies
16 that actually promote investment in new discoveries. And
17 that translates into hope for Pennsylvanians, people like
18 my family.

19 So, I'm going to give you three recent examples.
20 First, because of innovative medicines, hepatitis C is
21 actually curable in 90 percent of cases these days. We
22 also just saw the single biggest drop in a single year of
23 cancer deaths according to report that just came out from
24 the American Cancer Society only a couple weeks ago. And
25 they attributed that in large part to new medicines. More

1 than half the people in Pennsylvania have high cholesterol,
2 but new medicines are actually changing the way we treat
3 it, and there's been a 36 percent drop in deaths in the
4 last decade.

5 But those are just the medicines we have today.
6 There are 8,000 medicines in the pipeline right now, and
7 that process is risky, and it's complicated. It takes on
8 an average a decade and an estimated \$2.6 billion to bring
9 a drug to market. And unlike a lot of products we see
10 today, those drugs are being developed in America by
11 Americans, including Pennsylvanians where our industry is a
12 really important part of the State's economy.

13 More than a quarter million of Pennsylvanians are
14 employed in jobs that are supported by our industry, and
15 those are good-paying jobs. Those individuals are paid
16 nearly twice the salary of the average worker in this
17 State. Those treatments, they won't help people who can't
18 afford them, and we know that.

19 We know that for far too many Pennsylvanians the
20 health care system as it is right now is just not working
21 for a lot of the reasons that Antonio and Jane and others
22 have talked about. There aren't any easy solutions, but
23 patients here need leadership from all stakeholders to
24 figure out how to make it work better.

25 And we believe affordability for patients is

1 paramount. But it is a myth that the price of prescription
2 medicines are skyrocketing. I'm going to go back to
3 something Antonio said a little while ago. Net prices for
4 medicines grew .3 percent in 2018, .3 percent. That's
5 roughly in line with inflation. Now, compared to other
6 segments of the health care system, growth in drug spending
7 is actually pretty small. Over the last 10 years, both
8 hospital care and physician care grew more than drug
9 spending. In fact, prescription medicines contribute only
10 14 percent to overall health care spending. That's a
11 pretty small slice of the pie.

12 And, to make matters worse, our pharmaceutical
13 supply chain, as a lot of people have already talked about
14 today, has only grown more complicated over time. We've
15 already talked a lot about PBMs, whose job it is to
16 negotiate really steep discounts and rebates off of
17 prescription medicines. Their job is to work on behalf of
18 insurance companies. They are not working to make drugs
19 cheaper for patients.

20 So, as Antonio said, nearly half of all spending
21 on brand medicines is going to stakeholders and not the
22 companies who research, develop, and manufacture the drugs.
23 Let me say that again. Nearly half of all spending on
24 drugs is not going to drug companies. Rebates and
25 discounts, as Antonio mentioned, have doubled to \$166

1 billion. And it's not just the PBMs. They're not the only
2 ones at fault here. The amount health care providers,
3 including hospitals and pharmacies, are retaining actually
4 doubled between 2013 and 2018.

5 And it's not a blip; it's a trend. If you look
6 at slide 8 of my presentation, you'll see a chart. What
7 this chart tells you is that PBMs and entities like PBMs
8 have received a larger and larger share of total spending
9 over the last eight or so years. The author of this study,
10 which actually just came out last month, believes that over
11 the next couple years those trendlines are actually going
12 to cross meaning that manufacturers are actually going to
13 wind up keeping less than other entities in terms of
14 spending on drugs. We're going to keep less.

15 Now, for certain medicines like asthma, high
16 cholesterol, diabetes medicines, rebates can take up to 70
17 percent off the list price of a drug, so as payers and PBMs
18 use their not-insignificant leverage to demand lower prices
19 for drugs, patients keep paying more at the pharmacy
20 counter. And I think that's something everyone who's
21 talked here today can agree on. Everyone in this scenario
22 is winning except for the patient. For more than half of
23 commercially insured patients, their out-of-pocket spending
24 for brand medicines is actually based on the full list
25 price of the drug meaning they're not seeing the benefit of

1 those discounts and rebates.

2 And, as you can see on slide 10 for those of you
3 who have the slides, in some instances a patient could
4 actually wind up paying more than their insurance company
5 for a medicine. In this example, the list price of the
6 patient's drug is \$400, and they pay a 25 percent
7 coinsurance, which isn't all that uncommon these days,
8 meaning that they're going to pay \$100 at the pharmacy
9 counter. But their payer negotiated a 65 percent rebate
10 off the price of the drug, meaning they pay \$140. And the
11 patient is giving them \$100 back. That means that the
12 patient is paying \$100 for a drug that their insurance
13 company is only paying \$40 for. The health care system
14 isn't working for this patient, and it's not working for a
15 lot of Pennsylvanians.

16 Now, a lot of payers have claimed that sharing
17 discounts with patients would actually cause premiums to
18 skyrocket, so they'd just wind up paying for it somewhere
19 else, but that's not true. On slide 11 you can see that
20 sharing savings with patients would actually increase
21 premiums by 1 percent at most.

22 And research has shown that passing through
23 rebates and discounts could improve affordability. So,
24 take diabetes patients for example. Sharing 100 percent of
25 rebates with diabetes patients would decrease their out-of-

1 pocket costs by 40 percent or \$791 per patient per year.
2 That's a lot of money. It would also reduce other
3 avoidable costs, things like ER visit, hospitalizations,
4 which our system spends so much money on, to the tune of
5 about \$435 million a year.

6 And this kind of relief is desperately needed.
7 More than half of health plans now have deductibles, and
8 those have increased 360 percent since 2006. That means
9 patients are having to pay more for longer at the beginning
10 of their plan year before their insurance company starts
11 helping them out with their out-of-pocket costs.

12 And it's not just deductibles. Over the last
13 decade, the number of plans that have four or more tiers of
14 cost-sharing has actually increased to 44 percent. And
15 when you have more tiers of cost-sharing, that usually
16 means higher costs because higher tiers mean more patients
17 are paying coinsurance, and a coinsurance is a percent off
18 the list price of the product meaning you're not benefiting
19 from those rebates and discounts.

20 And that brings me to the reason we're all here
21 today, right? How do we fix this? The wrong way is
22 through policies that would let a government or an
23 organization like ICER set prices for medicines like the
24 United Kingdom and Germany and places in Europe do. That
25 type of policy threatens access, and it threatens

1 innovation. We have clear evidence of this. We don't need
2 to experiment. In foreign countries where the government
3 sets prices for medicines where they use affordability
4 boards, places like the U.K., Germany, and France, they
5 have access to far fewer innovative medicines than we have
6 here.

7 There's also clear evidence that this type of
8 policy has a negative impact on innovation. So, in 1986
9 the U.S. actually trailed Europe in biopharma R&D
10 investment by about 24 percent. Today, Europe trails us by
11 40 percent. We can't afford to lose that innovation. We
12 can't afford to lose the research that could lead to the
13 next cure for Alzheimer's or ALS or cancer. We need
14 solutions that are going to help patients afford their
15 medicines and not increase barriers to access and not take
16 away their hope.

17 So, here are solutions:

18 First, we must require that insurers and PBMs
19 pass those rebates and discounts that they receive from us
20 along to patients.

21 Second, in some cases, insurers aren't allowing
22 the coupons that manufacturers provide to patients to count
23 towards their deductibles. So, we provide millions and
24 millions of dollars in assistance to patients every year in
25 the form of coupons, free drugs, but insurers aren't

1 letting them count them towards deductibles, which means
2 patients are paying thousands more at the pharmacy counter
3 than they really should be.

4 Third, patients need to have more choices when it
5 comes to medicine coverage. Health insurers need to offer
6 at least a couple of plan options where medicines are
7 actually excluded from the deductible and where their cost-
8 sharing is just based on set copays, not coinsurance based
9 off of a list price of a drug.

10 Additionally, it's really important to Pharma
11 that our industry does our part. Pharma member companies
12 have created the medication assistance tool or what we call
13 MAT. It's a website, and it gives patients, your
14 constituents, caregivers, physicians information on where
15 they can find financial assistance from our companies. It
16 also links to member company websites where you can find
17 out about the cost of prescription medicines. So, we
18 talked a little bit about transparency earlier. That
19 information is on our member website. If you go to MAT,
20 you can find links to those places, and you can learn about
21 the cost of drugs. We think transparency is important.

22 So, in closing, innovation really depends on
23 having a U.S. market that's three things: free,
24 competitive, and predictable. These solutions have the
25 potential to vastly improve that market. We want to make

1 the market work better and help patients afford their drugs
2 and thrive without financial hardship. And we look forward
3 to working with the Committee and all the other speakers
4 today to create such change. Thank you again for having
5 me.

6 MAJORITY CHAIRWOMAN RAPP: Thank you very much,
7 Lauren. If you would just like to keep your seat there,
8 and I'll invite Sarah back. And if we can get Antonio back
9 on the screen.

10 MR. CIACCIA: All right. Are we back?

11 MAJORITY CHAIRWOMAN RAPP: We are back.

12 MR. CIACCIA: All right. Well, let me first
13 apologize. I think I broke my promise to Whitney --

14 MAJORITY CHAIRWOMAN RAPP: Okay. Hold on just --

15 MR. CIACCIA: -- that I would be a little bit
16 quicker.

17 MAJORITY CHAIRWOMAN RAPP: Hold on just a second.

18 MR. CIACCIA: I'll get --

19 MAJORITY CHAIRWOMAN RAPP: Can you hold on just a
20 second?

21 MR. CIACCIA: Absolutely.

22 MAJORITY CHAIRWOMAN RAPP: Okay. For the Members
23 and the public, I did want to inform you that we did
24 request representation from insurance, but they were not
25 able to provide us with a presenter today, so that door is

1 always open just for your information. We certainly can
2 always conduct another hearing, and they are always welcome
3 to the table.

4 So, at this point in time I am going to open the
5 remaining time. And it's currently 11:10. I think we had
6 planned for about 11:30. If we want to go a little bit
7 longer, that will be determined by our presenters, so if
8 you want to endure a little bit longer, that's -- or we can
9 conclude at 11:30.

10 So, Chairman Frankel, did you have a question?

11 DEMOCRATIC CHAIRMAN FRANKEL: Thank you. I mean,
12 I really appreciate the Chair putting this hearing
13 together, and I think it's obviously an extremely important
14 thing that we do get talked to by our constituents
15 constantly.

16 I guess I missed the beginning. Ms. Neves?

17 MS. NEVES: Neves.

18 DEMOCRATIC CHAIRMAN FRANKEL: Neves? Thanks.

19 MS. NEVES: It's hard to pronounce.

20 DEMOCRATIC CHAIRMAN FRANKEL: The issue of, you
21 know, the comparison between us and countries where there
22 are --

23 MS. NEVES: Sure.

24 DEMOCRATIC CHAIRMAN FRANKEL: -- price controls,
25 I mean, it has always occurred to me -- and I think our

1 first presenter spoke to this. When you take a look at
2 health care costs in the United States compared with the
3 developed economies around the country, whether they're in
4 Europe, Canada, or Asia --

5 MS. NEVES: Yes.

6 DEMOCRATIC CHAIRMAN FRANKEL: -- they are
7 spending half of what we do on health care, and they have
8 those controls that you talked about. And their results,
9 contrary to what I think you were implying in terms of life
10 expectancy, infant mortality, and chronic illness, you
11 know, put us to shame in terms of health care outcomes.
12 So, we're paying twice as much. Pharmaceutical costs are
13 increasingly becoming more and more of that part of the
14 equation. So, that's a concern. And I think also our
15 first presenter talked about the fact that to a certain
16 extent what the pricing mechanisms are here in the United
17 States, part of that is basically being used to subsidize
18 lower pricing in these other countries where there are some
19 price controls. So, you know, there are so many issues
20 here at the end of the day that are of concern.

21 And I also wanted to ask you, you know, we heard
22 that pharmaceutical companies can already provide point-of-
23 sale rebates. Is there anything stopping them from doing
24 that to help consumers right away without us coming in to
25 do that? So, maybe --

1 MS. NEVES: I can take all of it.

2 DEMOCRATIC CHAIRMAN FRANKEL: And both of you can
3 weigh in.

4 MS. NEVES: I would welcome Antonio and Sarah to
5 also jump in.

6 MAJORITY CHAIRWOMAN RAPP: Antonio is on the
7 screen --

8 DEMOCRATIC CHAIRMAN FRANKEL: And Antonio, right.

9 MS. NEVES: Yes, he's right there. So, I saw the
10 chart Antonio presented about health expenditures and
11 health outcomes, and I think that's a really good question
12 you're asking. So, drugs can't solve all health care
13 problems. There's a lot of lifestyles and societal factors
14 that go into those health outcomes. You mentioned infant
15 mortality, you know, you mentioned life expectancy. There
16 a lot of things that go into it.

17 In the disease areas where drugs actually do make
18 a difference, life expectancy is better here. So, what
19 Antonio showed you was for everything overall. It's for
20 general health outcomes measure. So, for example, cancer,
21 let's take that as an example. Life expectancy for people
22 with brain cancer, for children with brain cancer in the
23 U.S. is 40 percent higher than it is in the United Kingdom,
24 and that's because we have good drugs to treat it. So, on
25 things like cancer, chronic conditions, things where drugs

1 are actually helpful, we actually have better health
2 outcomes. So, that's the piece of the narrative that I
3 think is missing. So, I just wanted to respond to that
4 directly.

5 In terms of point-of-sale rebates, so we can't
6 offer point-of-sale rebates directly. That's for the
7 pharmacy benefit managers and the pharmacies to do. So,
8 those prices would have to be passed on by them. So, the
9 ball is in their court. As you said, they're not here to
10 defend themselves, but that's what I would say.

11 MAJORITY CHAIRWOMAN RAPP: [inaudible] the
12 microphone?

13 MS. NEVES: I'm sorry. I just don't want to get
14 too close to it. The flu is going around.

15 MS. EMOND: I can chime in on that a little bit
16 if that's all right. I had the pleasure of knowing Uwe
17 Reinhardt, who was a beloved health economist from
18 Princeton who passed away last year. And he is famous for
19 saying it's the price of stupid. Prices are a conscious
20 choice that impacts access. And so we have a situation
21 where there is no bound on what manufacturers can charge.

22 And Lauren is right that there's some evidence
23 and some research that shows we might have less innovation
24 if we had some downward pressure on prices, but the most
25 recent analysis of that was actually done for H.R. 3,

1 Pelosi's drug pricing bill, which predicted line 8 to 17,
2 fewer drugs over 10 years I think was the analysis. Am I
3 close? And what commentators have chimed in and said it's
4 very likely those fewer drugs would be those me-too drugs
5 that offer very little improvement for patients, and it's
6 not going to be things like the \$2.1 million gene therapy
7 that cures children of SMA, which ICER judged was a fair
8 price.

9 So, it's not about whether or not we are going to
10 have the same number of drugs approved and developed. It's
11 are they the ones that are actually benefiting patients?

12 MAJORITY CHAIRWOMAN RAPP: Thank you. Antonio,
13 did you want to weigh in on that question?

14 MR. CIACCIA: Yes, thank you very much. What I
15 would say is that it's really hard to predict what policy
16 is going to do to innovation in the future. So, I would
17 take any of those -- while it's important to consider those
18 things, I typically take them with a grain of salt because
19 it's very hard to determine how the market is going to
20 respond.

21 Moving to a system where you move the rebates to
22 the point of sale I would argue is probably better than the
23 current model that we have today, but I would caution you
24 back to one of the slides I pointed out before is rebates
25 don't create a system of winners and losers. And so if

1 you're pushing those prices through, congratulations,
2 you've pushed them back to the patient. You've essentially
3 sterilized what little arbitrage there could be going on on
4 branding rebates, but you still have the system where your
5 small commercial payers and your patients that pay out-of-
6 pocket, essentially, have very limited resources and
7 leverage to push back into actually yield a higher rebate
8 relative to what a government payer would or what a large
9 employer could, so you still have a system of winners and
10 losers, and you still have a sleight-of-hand on who gets
11 the benefit, how the net price is set from payer to payer
12 to payer.

13 MAJORITY CHAIRWOMAN RAPP: Thank you. I believe
14 our next question comes from Representative DeLissio.

15 REPRESENTATIVE DELISSIO: Thank you, Madam
16 Chairwoman.

17 Lauren, I believe you said about \$90 billion with
18 a B is spent on research and development?

19 MS. NEVES: That's right.

20 REPRESENTATIVE DELISSIO: And that's annually and
21 about \$30 billion with a B is on marketing?

22 MS. NEVES: Yes.

23 REPRESENTATIVE DELISSIO: Is that marketing to
24 the consumer or is that marketing to the licensed health
25 care provider, who is the only individual who can give

1 access to what's being marketed?

2 MS. NEVES: That's a good question. It's all of
3 it, so we use a relatively, you know, generous term for
4 marketing or definition for marketing because we don't want
5 to underestimate it, so it includes both direct and
6 consumer advertising. It includes marketing to physicians.
7 It includes marketing to everybody.

8 REPRESENTATIVE DELISSIO: Just as a follow-up,
9 can you please tell me the point of marketing to consumers?
10 They are not licensed health care providers. They have no
11 way of really evaluating that. Some of them may have some
12 background in it, but the majority of consumers are indeed
13 just patients. Their information and their world is
14 limited in terms of health care, so they are simply going
15 to go to their health care provider to parrot a commercial
16 that they saw on TV or an ad they saw on social media to
17 bring that to the -- and I'm doing this because money in
18 the system, like these costs are a lot, so --

19 MS. NEVES: Well, thank you for the question. I
20 think it's a good one. You know, I think when you see
21 directed consumer advertising as empowering patients. You
22 know, not a lot of patients have access to information
23 about the drugs that are available to them, and sometimes
24 they need to be their own champions. You know, my father
25 has wet AMD, age-related macular degeneration. And he went

1 to see an ophthalmologist, and that ophthalmologist told
2 him he'd likely be blind in a couple of years. But then he
3 did his own research on drugs, including look at, you know,
4 websites for companies that I directed him to, and he found
5 a treatment that actually works for him. And his, you
6 know, degeneration of his vision has been halted.

7 So, I understand why you're asking that, but I
8 think in some ways that information can really empower
9 consumers to go talk to their physicians and ask them about
10 their options. You know, physicians are the gatekeepers to
11 medicine, but they don't always have all the answers. They
12 don't always know what's best for their patients.
13 Sometimes the patient really has to decide what's best for
14 them.

15 REPRESENTATIVE DELISSIO: I'm all for consumers
16 being their own advocates. And just a general comment,
17 Madam Chair. This should not be this hard. We are talking
18 about rebates and pricing and point-of-sale.

19 MS. NEVES: I agree.

20 REPRESENTATIVE DELISSIO: I mean, my heavens,
21 this part right then and there, this should not be this
22 hard. We should not be tweaking and manipulating a system
23 that already today appears to be severely manipulated to
24 get this particular commodity to folks who need it.

25 MS. NEVES: Absolutely.

1 REPRESENTATIVE DELISSIO: Thank you.

2 MAJORITY CHAIRWOMAN RAPP: Thank you,
3 Representative. Representative Brad Roae.

4 REPRESENTATIVE ROAE: Thank you, Madam
5 Chairwoman. My question -- you know, a couple of you might
6 want to weigh in on this to answer the question, but the
7 concerns I get most for my constituents, you know, involve
8 insulin, you know, for diabetic treatment. Why is that one
9 so much more expensive? And does insurance cover that the
10 same way as other things, or is it just it's so expensive
11 they have to pay more with deductibles and copays and stuff
12 like that?

13 MS. NEVES: Do you want to take that?

14 MS. EMOND: I can. I mean, it is just like every
15 other class where there's competition, so you can have very
16 similar things that happen in rheumatoid arthritis, and
17 psoriasis. What's happening is the PBMs are able to
18 extract very large rebates in order for preferred formulary
19 placement, and then they have an incentive to drive their
20 members to those even when there are cheaper out-of-pocket
21 options available. So, this is a perfect poster child for
22 the dysfunction of the system.

23 What's interesting about insulin is that there
24 could be the caps for some States have been thinking about,
25 and that's addressing a symptom of the problem. It's not

1 addressing the problem itself. Remember that out-of-pocket
2 costs, coinsurance, deductibles are the reaction from the
3 employer community to try to maintain access to health
4 insurance for its employees while still being able to do
5 things like give wage increases. So, this type of cost
6 shifting, while important and very worthy of policymaker
7 attention, is a symptom of a broader problem. If you had a
8 system with no rebates -- this is one we contemplated. It
9 was put forth by the Trump Administration. We even have a
10 white paper about this if anyone wants to nerd out about
11 it. There are theories that premiums would increase
12 because of those savings.

13 But I will go back to what Antonio said earlier.
14 Right now, if premiums are lower because we're cost
15 shifting to people with chronicle illnesses, that's the
16 opposite of what health insurance is supposed to do because
17 that means the sick is subsidizing the healthy.

18 MS. NEVES: I'll weigh in really quickly here
19 since you asked about our drugs. So, we offer millions and
20 millions of dollars in assistance to people to help them
21 afford their insulins. And I would make an argument, like
22 I did in my presentation, that those rebates and discounts
23 we're giving to PBMs should be passed on to patients. It
24 could save them a lot of money. It would save the system a
25 lot of money.

1 I would also note that we are supportive of out-
2 of-pocket caps on insulins like many States have done. So,
3 pharma, you know, supports limiting patients' exposure in
4 terms of copays to insulins.

5 MAJORITY CHAIRWOMAN RAPP: Yes. Antonio, did you
6 want to weigh in on the insulin question?

7 MR. CIACCIA: Yes, absolutely. So, two things
8 specifically. Both very correct, previous speakers. Any
9 competitive class of drugs -- this is where, you know, my
10 frustration with the system goes. In a traditional
11 marketplace -- remove yourself from drugs, think of
12 anything. In a marketplace with high competition,
13 typically, you have providers' said product competing on
14 price and service. And what that does is it typically
15 increases the quality and it lowers the prices as each
16 manufacturer of said product works to undercut the other in
17 order to gain market share.

18 In a system that's predicated on rebates, you
19 actually remove that traditional market function. Instead
20 of manufacturers in the drug space competing on price to
21 lower the price, they actually compete with one another to
22 raise the price to make way for higher rebates to pass
23 through back to the supply chain. So, competition works in
24 the exact opposite effect in the drug industry. Heavy
25 competition typically means that high gross-to-net bubble,

1 high list prices, very high rebates. Those who, again, get
2 exposed to more of that price are impacted
3 disproportionately.

4 The second thing is is the insulin marketplace is
5 not lending itself substantially to generic competition, so
6 there are generics that have hit the marketplace, but
7 insurers and PBMs are chasing the rebate instead of
8 bringing the generic version onto the formulary. So, you
9 traditionally would see a generic drug hit the marketplace
10 and totally upend the brand manufacturer that it seeks to
11 copy. Insulin, we're seeing the exact opposite occur where
12 generic comes to market and nobody's covering it.

13 REPRESENTATIVE ROAE: So, just real quickly,
14 Chairman, so we might be better off -- I'm not saying we
15 can't do both, but rather than passing a law like Colorado
16 that says the patient only has to pay 100 bucks a month, we
17 might be better off if we can do this, pass some kind of
18 law that would make more generics available to bring down
19 the cost.

20 MS. NEVES: And I would note that more generics
21 are on the way. As was noted I think by Jane, you know,
22 these drugs have a finite patent life, and a lot of these
23 are going generic in the next couple years. So, you know,
24 the money that we make now we put back into developing
25 better, innovative drugs for, you know, diabetes for the

1 same things, and then at the end of that patent life, the
2 system reaps the reward. So, I just wanted to note that as
3 well.

4 MAJORITY CHAIRWOMAN RAPP: Thank you,
5 Representative. I'm going to move to Representative Daley.
6 I believe you have to leave, so please go ahead with your
7 question.

8 REPRESENTATIVE DALEY: Thank you so much. One of
9 the questions is -- I think I read it in our testifier who
10 was not able to be here today, and I don't think anybody
11 mentioned this, but the wholesalers that are in the middle
12 of this, is this another group that we should be looking at
13 their role in the path from drug company to drugmaker to
14 patient?

15 MS. METZLER: You do have written testimony in
16 your packet, and that is from the organization that
17 represents the wholesalers.

18 REPRESENTATIVE DALEY: Okay.

19 MS. METZLER: So, we have asked. The date did
20 not work for them, so they did provide written testimony.
21 But we have them on standby if we have a second hearing.

22 REPRESENTATIVE DALEY: Okay. I happen to have a
23 big one -- I just should say this probably. I happen to
24 have a big one moving into my district with their worldwide
25 headquarters, right down the street for my district office.

1 It's a big change that's happening. Can I ask another
2 question?

3 MAJORITY CHAIRWOMAN RAPP: Yes, you may.

4 REPRESENTATIVE DALEY: Thank you. Thanks. This
5 is a question related to the ICER. You said that you have
6 this whole protocol for evaluating the fairness of the
7 price of the drug.

8 MS. EMOND: Correct.

9 REPRESENTATIVE DALEY: So, I mean, how do you
10 then deal with if the fair price of the drug is actually
11 very expensive --

12 MS. EMOND: Right.

13 REPRESENTATIVE DALEY: -- what are the next
14 steps?

15 MS. EMOND: So, we have no regulatory authority,
16 so actually no one has to do what we say, which is what I
17 often say to groups who are very worried that somehow
18 there's going to be some sort of influx of ICER reports
19 that say patients can't get access to their care because
20 that's not ever what we do. What we do is further public
21 conversation because, right now, payers make these
22 decisions about coverage access, and manufacturers make
23 decisions about price behind closed doors with no patients
24 anywhere. They even have gag clauses in the agreements
25 they sign with each other that say I can't tell you what

1 discount I'm giving you and you can't tell anyone what
2 discount I'm giving you, and so there's all this secrecy
3 around the status quo.

4 By moving the conversation out into an eight-
5 month public process, we're trying to further a grown-up
6 conversation about how we pay for health care with limited
7 resources. And what I can tell you is absent and without
8 regulatory authority, lots of people are using our work
9 because they look to it as the independent assessment of
10 whether or not they're getting ripped off.

11 There are times when we say our price is fair.
12 There are times when we say the price could actually be
13 higher and still be fair. But the majority of our work,
14 about 85 to 90 percent of the time we show that the prices
15 chosen by the manufacturer is higher than that of the
16 clinical benefit that the patients are receiving.

17 REPRESENTATIVE DALEY: So, if you think about
18 that there's no such thing as a free lunch, you're
19 substantiating that. And it's one of the things that -- I
20 don't know, I have a personal pet peeve when I hear all of
21 these things are free because I feel like, well, somebody's
22 paying for that. Senior citizens gets to pay nothing for
23 public transportation, but that's only because the lottery
24 is bringing in dollars to pay for it, so it's just one of
25 those interesting conundrums I think that we have when you

1 think about low cost and it's free, that there's somewhere
2 a cost. And so I think that's really interesting, the fact
3 that you have this kind of a protocol and are looking at it
4 in that way, so thank you.

5 MS. NEVES: So, can I make one comment in
6 response to that? I just want to respond. When ICER says
7 that the drug is cost-effective or high-value, that's not a
8 guarantee of access. And I think Sarah would agree with
9 me.

10 MS. EMOND: That's correct.

11 MS. NEVES: You know, they don't say very often
12 that drugs are high-value, but one key example I would say
13 is psoriasis treatments, which ICER found to be very high-
14 value, I believe, and cost-effective due to a lot of
15 patient engagement in that process and a lot of engagement
16 from our member companies. Access actually got worse to
17 those drugs after ICER's report came out. Utilization
18 management restrictions, things like prior authorization,
19 the things that keep you from just getting your drug got
20 heavier and worse after ICER came out with their review, so
21 I just wanted to point that out. It's not --

22 MS. EMOND: Because the price went up and they
23 were no longer cost-effective.

24 MAJORITY CHAIRWOMAN RAPP: Thank you. And I
25 think the point is very well taken that nothing is free.

1 We have a lot of taxpayers supporting a lot of what happens
2 with our pharmaceuticals for people.

3 Antonio, did you want to weigh in on that
4 question?

5 MR. CIACCIA: No, that's fine.

6 MAJORITY CHAIRWOMAN RAPP: Okay. Our next
7 question comes from Representative Zimmerman.

8 REPRESENTATIVE ZIMMERMAN: Thank you, Madam
9 Chair.

10 So, I'd be interested in hearing what the impacts
11 of like a right to try that was passed has on this whole
12 conversation from rebates to cost to drug manufacturing and
13 the likes of that, so --

14 MS. NEVES: I can weigh in.

15 MS. EMOND: I'm very interested -- Lauren
16 probably can teach me a little bit about this. What I have
17 heard -- and so she's probably heard more directly, but
18 from the manufacturers that we talk to, very few are
19 actually participating in the right to try initiative. And
20 I think in some ways that's a very positive sign from the
21 pharmaceutical industry because they believe in the process
22 of conducting clinical trials to prove that the drug works
23 and is safe and effective, and they believe in the FDA
24 process. And so the fact that you're not seeing a lot of
25 manufacturers willingly give their drug over -- now, the

1 cynical side of me says it's also probably because of fear
2 of litigation and all of those other things, but, I mean,
3 that's a probably fair risk-averse behavior in this manner.

4 I would say that the social contract that we have
5 developed is that society pays for a drug after a
6 manufacturer proves it works, right? Like that's the
7 social contract. That's why we have the FDA process. What
8 I feel is -- what I have heard from many policymakers is
9 they feel like the social contract has been broken in some
10 regards. The FDA has lowered some of the evidence
11 standards through accelerated approval in order to get very
12 important drugs for very important conditions to patients
13 faster, and in exchange has required lower bars for
14 evidence generation. And the social contract would then
15 say, well, perhaps you shouldn't charge \$500,000 a year for
16 this new drug because you're still developing the evidence
17 to prove the clinical benefit for patients.

18 So, it's a bit related to your question about
19 right to try. We do have a change in the level of evidence
20 that we are seeing at approval because of some statutory
21 things that the FDA is doing, and that should prompt us to
22 think about what the fairness of the price is in that
23 regard as well.

24 MS. NEVES: So, I'll comment on right to try.
25 You know, right to try is tricky. I really understand the

1 desperation that a lot of people who want those drugs feel.
2 I understand the desperation of having a sick child and
3 just wanting to try anything to make them better. But the
4 motto of our industry is do no harm. You know, we want to
5 help people. And until drugs have been through that
6 process that Sarah just spoke to, the FDA process, which,
7 to be clear, is the gold standard for safety and efficacy
8 throughout the world. We have the highest standards of
9 anywhere in the world. It makes us very, very hesitant to
10 give people access to a drug that we don't know meets that
11 standard because we don't want to hurt those people. We
12 don't want them to be in more pain than they currently are.
13 So, it's certainly a difficult position to be in, and we
14 certainly have sympathy for them.

15 I would say, just responding to Sarah's point
16 about accelerated approval, that program was created
17 because we want to get drugs to patients who don't have a
18 lot of time left, sooner. We want them to go through the
19 FDA process, but it's a lot of the same issue that you're
20 talking about. Those people don't have time, people like
21 lung cancer patients or patients with terminal diseases.
22 We want them to not have to wait for the FDA's entire
23 process to get access to those drugs. That's why those
24 pathways exist. But those drugs still meet the evidence
25 standards the FDA supports. And again, those evidence

1 standards are the highest in the world. So, I hope that
2 answers your question.

3 MAJORITY CHAIRWOMAN RAPP: Antonio, did you want
4 to weigh in on the right-to-try drugs?

5 MR. CIACCIA: Ohio passed right-to-try a couple
6 years ago, and, you know, this is a personal comment. I
7 think it's nice to have patients have that outlet. My
8 grandfather, who lives in Moon Township, you know, he has
9 amyloidosis, and there was a drug that doctors felt would
10 be useful for him but that had not made it through the
11 pipeline yet. And as somebody who is very selfishly in
12 love with my grandfather, we were anxiously awaiting its
13 approval. And I would like to think that we could have
14 options available to us if they're not necessarily through
15 the pipeline altogether, but that's more of a personal
16 opinion.

17 MAJORITY CHAIRWOMAN RAPP: Thank you.
18 Representative Keefer.

19 REPRESENTATIVE KEEFER: Thank you. So, getting
20 back to the root of the problem and where we're at, so on
21 average could you tell me how much -- like what percentage
22 of the drugs are discounted or rebated? What percentage of
23 all the drugs that you --

24 MS. NEVES: Yes, that's part of the answer. As
25 Sarah said, it depends in part on who you ask, but it also

1 depends highly on what drug you're talking about. I'm
2 hesitant to give you any kind of number specifically --

3 REPRESENTATIVE KEEFER: Is --

4 MS. NEVES: -- just because it's hard to pin that
5 down.

6 REPRESENTATIVE KEEFER: Is there any drug that
7 you don't discount, you know, when you have that third-
8 party, any of them that you don't --

9 MS. NEVES: Sure.

10 REPRESENTATIVE KEEFER: -- discount or have a
11 coupon for? I mean, it seems like, you know, I go to buy a
12 car and it's listed at, you know, \$60,000, but I know I'm
13 not going to pay -- so, again, getting back to that, is
14 there something that could be -- I'm not advocating for the
15 State to come in and dictate what prices are, but I am
16 saying you as the manufacturer looking at it saying, you
17 know what -- you could almost independently cut out that
18 third party by just saying, hey, this is how much this drug
19 is, period without all that. You know, the cost-benefit
20 analysis of doing that across the board would at least get
21 rid of one level.

22 MS. NEVES: Yeah, and I think what Sarah is about
23 to say is that there aren't rebates and discounts on all
24 the drugs, and that's accurate. You know, there are
25 certain drugs that we don't discount as heavily as others.

1 I mean, manufacturers make up for, you know, discounts in
2 certain places by charging the full price sometimes for a
3 drug for a certain period of time. And, again, I just want
4 to reinforce that price only lasts until that drug goes
5 generic or has a biosimilar competitor. So, even when they
6 are, you know, asking for a full price of a drug, that's
7 usually a time-limited option. And, again, we're
8 supportive of passing rebates and discounts along to
9 patients. That was my number one solution, and I believe
10 that we should do that.

11 You also mentioned, you know, coupons and
12 assistance for drugs that we don't necessarily offer
13 discounts or rebates on. I would say there's two things.
14 First of all, people have insurance for reason. They pay
15 insurance premiums or their employers oftentimes pay very
16 high insurance premiums so they can get help with the cost
17 of that drug.

18 Second, I would just go back to the point that we
19 offer free drugs, millions and millions of dollars in free
20 drugs and copay assistance to patients. So, I'd like to
21 think there's a safety net for almost everyone out there.
22 Sarah, I'm happy --

23 MS. EMOND: No, thank you. So, you hit on a
24 really important point because the rebate and the gross-to-
25 net bubble gets a lot of attention. Antonio has done such

1 great work in this area. But it's for select classes, and
2 so we don't see a lot of rebating in oncology. We don't
3 see a lot of rebating in sole source. And that usually is
4 rare disorders where there's just one drug because, again,
5 it's market forces. There's no market incentive for the
6 manufacturer to offer a rebate for preferred formulary
7 placement because there is no other option. And then in
8 oncology it's just patently unpopular to try to do any
9 utilization management in oncology. And that's a
10 reflection of a social value honestly, right? We want the
11 cancer patients to be able to get access to what they need.

12 I did also want to mention in case it didn't come
13 through in my earlier testimony, when we do the analysis of
14 whether or not the price is fair, we're using estimated net
15 price, so we're trying to get through all of this talk of
16 rebates and discounts and who's getting what so we're able
17 to actually look at the data that exists on the average
18 discounts that are happening across payers, and oftentimes
19 we're still seeing the prices are much higher than the
20 clinical benefit patients are getting.

21 REPRESENTATIVE KEEFER: Can I ask one more?

22 MAJORITY CHAIRWOMAN RAPP: Antonio, did you have
23 a --

24 MR. CIACCIA: Real quick, an overwhelming
25 majority of the drugs are rebated in some way, shape, or

1 form. As a precondition for a drug to be covered within
2 the Medicaid programs, drug makers have to volunteer to be
3 part of the drug rebate program. So, most of the drugs
4 that are available in the marketplace are dispensed through
5 Medicaid, and by virtue of that, they have to be giving
6 rebates. So, the degree of rebate are very different from
7 drug to drug, class to class, but most drugs do see some
8 level of rebating and discounting.

9 REPRESENTATIVE KEEFER: Right, which goes back to
10 if it's going to be rebated anyway, you know, just putting
11 that actual amount out out of the gate. And one more
12 question, Madam Chair? So you said on average it's 10
13 years, \$2.6 billion for a drug to come online on average.
14 And what percentage of that is received from -- I know like
15 Pennsylvania we give different grant dollars and academic
16 dollars to different institutions, and you also have the
17 NIH. Is that factoring in those dollars as well?

18 MS. NEVES: \$2.6 billion, I'm not entirely sure
19 if that includes NIH dollars. I don't believe it actually
20 does. But I'm happy to talk a little bit about the NIH.
21 You know, the NIH does very basic important research. I
22 don't believe they're part of that \$2.6 billion. And they
23 spend far, far less on R&D than we do. Our marketing
24 budget, which I mentioned earlier, which is about \$30
25 billion, is about what they spend. That's the entire NIH's

1 budget. That's not even what they spend on drug
2 development. That's their whole budget. We spend \$90
3 billion, so I just wanted to get that point out.

4 MS. EMOND: No, no, no, absolutely. The \$2.6
5 billion is an estimate that comes from the Tufts Center for
6 the Study of Drug Development. And that includes the
7 outlay from the manufacturers themselves, including like a
8 biotech company that invested and then gets bought by a
9 bigger company. They're factoring all of that in.

10 It's important to note for any economists in the
11 room that a large portion of the \$2.6 billion is actually
12 what they call opportunity cost. It's the ability to not
13 have invested some of the R&D money in another asset that
14 might have been approved. And they claim that as part of
15 the money that is spent to develop a new drug because if
16 you dedicate your resources to developing drug A and not
17 drug B, you've missed potentially the possibility to have a
18 great drug with drug B. So, opportunity cost is in that
19 \$2.6 billion estimate, and so I think that's just an
20 important caveat.

21 REPRESENTATIVE KEEFER: Thank you.

22 MAJORITY CHAIRWOMAN RAPP: Antonio, did you want
23 to reply to the question on research?

24 MR. CIACCIA: Yes. I mean, the one thing that
25 just popped out at me was I've heard three big numbers

1 today, one of them we had in our slides, which is the
2 amount of rebates that are flowing through the system has
3 now reached \$166 billion. And then from the previous
4 testimonies I heard \$90 billion is being spent on R&D,
5 another \$30 billion is being spent on marketing. So,
6 literally if you take all the R&D and the marketing and
7 combine them, it's not nearly the amount of the amount of
8 discounts that drug makers are passing through the system.
9 That shows you just how significant that gap has become.

10 MAJORITY CHAIRWOMAN RAPP: Thank you. Our next
11 question comes from Representative Innamorato.

12 REPRESENTATIVE INNAMORATO: Great. Thank you,
13 Chairwoman. Thank you for being here.

14 Lauren, my first question is for you. So, you
15 talked a lot about the aggregate of your member companies
16 and how they've invested in new treatments and cures. I
17 was wondering if you had the aggregate number of how much
18 your member companies spend on CEO pay and benefit
19 packages?

20 MS. NEVES: I don't have that number off the top
21 of my head. I'm sorry.

22 REPRESENTATIVE INNAMORATO: Do you know how much
23 they've spent on stock buyback?

24 MS. NEVES: I don't.

25 REPRESENTATIVE INNAMORATO: Okay. I think that's

1 a very important number to look at, especially when we're
2 looking at private industry and the inflated cost of
3 pharmaceuticals because there's been, you know, reports
4 that there are pharmaceutical companies that are part of
5 your member organization that are spending money to buy
6 back their stock to return to shareholders as opposed to
7 potentially passing on cost savings to people who need to
8 use insulin and the like.

9 Do you have an aggregate number on how much you
10 spend on lobbying?

11 MS. NEVES: I don't have that number in front of
12 me right now. I certainly --

13 REPRESENTATIVE INNAMORATO: Okay.

14 MS. NEVES: -- can get it for you.

15 REPRESENTATIVE INNAMORATO: Okay. Because I
16 think that would be good for our comparative to look at
17 marketing and R&D in the context of overall expenses that
18 you have.

19 Which leads me into a second question. I know in
20 California they have introduced a bill to produce generics,
21 and I think like a publicly owned manufacturer who is not
22 driven by having to return values to shareholders could be
23 something that could help realign the market and just
24 wanted to kind of get your take on what introducing
25 something like that into the generic marketplace would mean

1 for patients and end-users.

2 MS. NEVES: So, I'm not a generic manufacturer.
3 I represent brand-name pharmaceutical companies, so I can't
4 really speak to that specific aspect of the California
5 proposal. What I would like to go back to is the lobbying
6 question. So, you asked me specifically how much we spend
7 on lobbying. I can tell you right now it's a fraction of
8 what we spend on R&D, which, as I've said multiple times
9 today, is \$90 billion.

10 I would also say that when it comes to how much
11 our CEOs earn, when you look at the top 20 earnings CEOs in
12 health care, we aren't in the top 10, but PBMs are. So, I
13 just want to again bring this back to a problem that's
14 about the whole system, not just us.

15 I'll let Sarah speak about the California
16 proposal.

17 REPRESENTATIVE INNAMORATO: Absolutely. And I
18 just want to say, too, if they were sitting here, too, I
19 would also ask them that question.

20 MS. NEVES: I know you would. I know you would,
21 but they're not here, so I'm going to talk.

22 MS. EMOND: The generic question is a really
23 interesting one because Lauren has mentioned this
24 beautifully already that, again, I talk a lot about social
25 contract, but the social contract is you get a period of

1 monopoly and then society benefits from that investment you
2 made in innovation by having a cheaper price. It's
3 unfortunate that we don't see that happening as readily as
4 I think a lot of us would in a lot of cases.

5 The original patent on Humira, the biggest
6 selling drug in the world, ran out a long time ago, but
7 they still have a patent thicket, as it's called, around
8 their IP that's preventing the introduction of a
9 biosimilar. And we can have a whole other session on why
10 no one is using biosimilars, and so I won't even dive into
11 that.

12 But back to the Representative's question. The
13 generic market is supposed to be sort of marginal cost for
14 making the drug and a tiny bit of profit to run your
15 business. Like that has been the way it's worked. What
16 you see with something like a Civica Rx, which is a
17 nonprofit generic manufacturer where large hospitals get
18 together, is they were reacting to the fact that they were
19 seeing shortages of drugs because there was one sole source
20 for the generic, and then there would be a shortage. And
21 then when it got reintroduced, they would jack up the price
22 because they had almost like a monopoly, but they're not a
23 brand, right? They didn't invest all of this money in the
24 R&D, so it was raising that question.

25 I don't know a lot about the California

1 legislation. I'm interested to know why they'd want to do
2 that and not potentially just join Civica Rx. And so that
3 could be something that Pennsylvania examines is can we
4 join Civica Rx, and then can we get the lower cost through
5 their nonprofit for our Medicaid, for our State? That
6 would just be my recommendation instead of like reinventing
7 the wheel and trying to get certified as a generic
8 manufacturer that's State-run, which I think would be a big
9 task.

10 MAJORITY CHAIRWOMAN RAPP: Antonio, do you have
11 anything to add?

12 MR. CIACCIA: Yes. Representative Innamorato,
13 I've studied a lot about this generic market check if you
14 will from California, and so a lot of our research,
15 essentially everything that we started doing predicated on
16 examining how the generic marketplace was working to drive
17 down prices and then to see how it was manifesting itself
18 in terms of cost on the other side of the spectrum, which
19 is what the payers end up paying. So, what we actually see
20 is that the generic marketplace, outside of these instances
21 where there are unique situations with shortages, shortages
22 inevitably do lead to price spikes and sometimes for a very
23 small utilization for drug that not a lot of people take.
24 Sometimes those price spikes could last for a really long
25 time. And so in that instance I do see an opportunity for

1 somebody to come in with essentially good-will nature to
2 come in and add competition back into a marketplace,
3 essentially disrupt it.

4 But our research has shown that a lot of times
5 when you see a price spike after a drug shortage, that
6 generic marketplace is still highly competitive. You could
7 see 20 different manufacturers of a generic drug at a
8 different time, and there's a healthy incentive there for
9 those generic manufacturers to constantly undercut each
10 other to try and maneuver their way to get market share
11 from pharmacies.

12 Because pharmacies get paid the same amount no
13 matter what drug they're dispensing, the incentive of the
14 pharmacy is to go out and buy the cheapest drug in the
15 marketplace. So, generic manufacturers are constantly
16 undercutting each other to try and entice the pharmacy
17 marketplace to go buy those drugs. That way the pharmacies
18 can increase their spread.

19 So, what we see is a very deficient generic --

20 FEMALE SPEAKER: Oh, we were doing so well. It's
21 on his end, yeah.

22 MAJORITY CHAIRWOMAN RAPP: We're going to go
23 ahead and move to then our last question from
24 Representative Gaydos. And then if we can reconnect with
25 Tony, he can finish what he wants to say there.

1 REPRESENTATIVE GAYDOS: Thank you, Chairman Rapp.
2 You know, first of all, listening to all this, it certainly
3 sounds like this pricing mess in the first place was caused
4 by government and then the reaction to government sticking
5 their hands in there. So, that's something that's always a
6 concern to me is that, you know, price-fixing never, ever
7 solves any problems.

8 The question I have is about the investment for
9 research and development. So, \$90 billion was thrown
10 around. Out of \$90 billion that is invested, how much of
11 that goes towards drugs that actually do come to the market
12 and, you know, what is that risk factor of pharmaceutical
13 companies?

14 MS. NEVES: Sure. That's a great question. So,
15 it is, as I said before in my testimony, a risky and
16 complicated process. I can't break down the \$90 billion
17 for you because I think it's also incredibly intertwined.

18 I would say that -- so, for example, I think this
19 number is since 2003, we've seen 143 Alzheimer's drugs go
20 through the pipeline and fall out. There are four still in
21 the pipeline. So, to the extent that that gives you a
22 sense of how complicated and difficult that is, it's
23 incredibly risky. So, there are failures, and that is a
24 part of every business, not just ours. That's a part of
25 manufacturing. That's a part of, you know, everything.

1 But because of the science and the complicated science,
2 especially these new biologics we're developing, it's
3 become even riskier and complicated. So, I would say that
4 the failures are part of that \$90 billion, and the failures
5 are how we get to the successes. That's how we're
6 eventually going to get to a cure for Alzheimer's disease.

7 REPRESENTATIVE GAYDOS: So, what encourages your
8 innovation? What encourages your innovation?

9 MS. NEVES: The patients, the getting the cures,
10 that's what encourages our innovation, the seeing
11 treatments that make a difference in people's lives.
12 That's what makes our scientists wake up every day and go
13 to work and keep trying. If you're a bench scientist, you
14 know that, you know, out of every 100 experiments that you
15 do, one is going to succeed, but that one could be a cure
16 for cancer, and that's why you keep going.

17 REPRESENTATIVE GAYDOS: So, ultimately, in the
18 end, the pricing that you get --

19 MS. NEVES: Yes.

20 REPRESENTATIVE GAYDOS: -- to pay back, so really
21 are prescription drugs really all that expensive given that
22 that money has to go back into innovation?

23 MS. NEVES: I'm not sure I followed that
24 question. Eventually, the money that we do make off of the
25 drugs that do succeed does feed back into innovation, and

1 that sort of starts the cycle all over again. So, that
2 answers your question I hope.

3 REPRESENTATIVE GAYDOS: Yes, it does.

4 MS. NEVES: Okay.

5 MAJORITY CHAIRWOMAN RAPP: Antonio, did you want
6 to finish your thoughts on that question?

7 MR. CIACCIA: No, it's okay. Thank you.

8 MAJORITY CHAIRWOMAN RAPP: I want to thank you.
9 Before I make closing remarks, I'll ask Chairman Frankel,
10 do you have any closing remarks that you'd like to give, or
11 questions?

12 DEMOCRATIC CHAIRMAN FRANKEL: I certainly
13 appreciate those who came to testify today to give us this
14 perspective on an issue that is incredibly complex and
15 frustrating for many of us. And I do think that while my
16 colleague from Allegheny County talks about the issues of
17 innovation and not having government engage in this,
18 government did help create this problem on the rebate
19 issue. I think we have a responsibility to help clean that
20 up. And one of the things just in my informal interactions
21 with different stakeholders on this issue, there's a lot of
22 finger-pointing all the time whether it's, you know, from
23 the pharmaceutical manufacturers to the PBMs to the payers.
24 We have to get beyond the finger-pointing.

25 But I do think that there is a role for

1 government to come into, and I do think that we need to
2 take a look at the manufacturing side. I understand the
3 need for research and development and to incentivize it,
4 but when you do take a look at the behavior of the
5 pharmaceutical companies with respect to, you know, the
6 executive compensation, when you take a look at the issues
7 that my colleague also from Allegheny County identified,
8 the stock buyback and trying to prop up stock prices which
9 have performed extraordinarily well, we have to be able to
10 balance out I think on an issue that strikes so intimately
11 in our families and our constituents that there is a role
12 for government to play to help fix this level, that we can
13 preserve innovation, we can preserve reasonable access to
14 people, and I do think that, you know, some of the ideas
15 that were thrown out today for a role for government to
16 play for legislation, some of which is playing out in other
17 parts of the country.

18 I'm not wedded just to the proposal that Mrs.
19 Horvath brought up, which I've introduced. There may be
20 other solutions, but we have opportunities to take a look
21 at how these play out. Maryland has adopted that model.
22 Maine has adopted that model. So, we'll have the
23 opportunity to kind of review are these are at.

24 But I do come down to the conclusion that, you
25 know, the idea of having a Public Utility Commission, we do

1 regulate things that are so meaningful to preserving
2 quality of life and preserving life itself, whether it's
3 access to water, gas, electricity, that pharmaceuticals
4 play a role in that same exact space to me in terms of
5 preserving life and quality of life for people.

6 So, we have a lot of work to do, and I really do
7 appreciate all the perspectives that we had here today.
8 And certainly for Chairwoman Rapp's interest in this and
9 putting this hearing together, I'm very appreciative.

10 MAJORITY CHAIRWOMAN RAPP: Thank you, Chairman
11 Frankel, kind words.

12 My thanks to all the presenters and all of your
13 time. I know that when you compile testimony, it's not
14 done in five minutes. And, Anthony, thank you. Antonio,
15 thank you so very much for your contributions here. We
16 truly appreciate it. I want to thank our IT department for
17 being here and helping us set this up. Hopefully, the
18 people on the overflow were able to view this downstairs.
19 We never know how many people to expect.

20 And I certainly agree with Chairman Frankel.
21 There's a lot of barriers that we see, you know, especially
22 in prescriptions. It certainly is a huge issue with our
23 constituents across the State of Pennsylvania. And we're
24 always willing to look at other States' legislation and
25 input on legislation that we could help ease the burden on

1 our constituents.

2 So, I want to thank each and every one of you,
3 and I also want to thank the staff. They do a great job
4 putting everything together, and I appreciate on both sides
5 of the aisle here.

6 And my thanks to the public for taking the
7 interest in being here and listening. So, I don't think
8 this will be the last of this type of hearing because this
9 is obviously an ongoing issue, so we definitely appreciate
10 all of your input. Thank you so much for being here, and
11 hopefully, we'll see you in the future. Thank you. Thank
12 you, Members. And the meeting's adjourned.

13

14 (The hearing concluded at 11:56 a.m.)

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2 are a true and accurate transcription produced from audio
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