Statement of David E. Mitchell
Founder, Patients For Affordable Drugs

before the

U.S. House of Representatives Subcommittee on Consumer Protection and Commerce
of the

House Committee on Energy and Commerce

for a hearing on

Protecting Consumers from Pharmaceutical Market Gaming Tactics

September 19, 2019

Chairwoman Schakowsky, Ranking Member McMorris Rodgers, Members of the Committee. I am honored to be here today.

Section I. Background and Introduction

My name is David Mitchell. I am the Founder of Patients For Affordable Drugs. We are a bipartisan organization focused on policies to lower prescription drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

In the two years since we launched, we have collected over 20,000 stories of patients struggling to pay high drug prices. And we have built a community of more than 150,000 patients and allies that mobilize in support of policies to lower drug prices.

More importantly for today, I have an incurable blood cancer, and prescription drugs are keeping me alive.

My story starts a little over eight years ago. I woke up with excruciating back pain, which I chalked up to activities and, of course, my age. On this particular morning, however, it was worse than ever before. Standing in my bedroom alone, I suddenly collapsed on the floor and couldn't move.

After visits to the ER and various doctors, I found out why I couldn't move — a crushed T-11 vertebra.

Cancer had literally broken my back.

Multiple myeloma attacks my bones. It broke my ribs and ate holes in my pelvis, arm bones, and skull. Doctors repaired my spine, and the fact that I can stand is a miracle of modern medicine.

Unfortunately, I will never be a cancer survivor. Multiple myeloma is incurable. But with expensive medication, I can keep it at bay for some period of time. Unless we invent a durable cure, I will be in continuous treatment until I die.

So every two weeks, I spend several hours at a local clinic getting an infusion of drugs that currently cost around $650,000 per year. That doesn't include my non-infused drugs. Once those are factored in, the total list price for my treatment right now is more than $875,000 per year.

I am very grateful for these drugs; they are keeping me alive. I have already relapsed twice. So the importance of innovation is not theoretical for me — it is literally life and death.

But my experience with cancer has taught me one irrefutable fact: Drugs don't work if people can't afford them.

Section II. The Cost of Drugs

From 2011-2016, prescription drug spending in the U.S. grew by 28%, which was more than 2.5 times inflation during that period.[1] Forty-two percent of cancer patients deplete their entire net worth within the first 2 years of treatment — in part due to high drug prices.[2] And drug spending growth is projected to accelerate by 31% by 2023.[3]

Telling Congress that drugs are too expensive feels a little absurd. This is the one issue just about everyone agrees on.

In fact, a recent poll from the Kaiser Family Foundation found that 70% of Americans say lowering prescription drug prices should be Congress' top health care priority. Respondents

[1] Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11 and BLS data on CPI-U 2011-2016.

[2] Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer. Gilligan, Adrienne M. et al. The American Journal of Medicine , Volume 131 , Issue 10 , 1187 - 1199.e5

[3] Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11.

ranked it ahead of addressing surprise billing and ensuring protections for people with pre-existing conditions.[4] People are hurting.

This makes my story far from unique.

When I first got sick, doctors put me on a drug called Revlimid. I was on an employer plan then, and my out-of-pocket costs were $3,250 per year for that one drug. I could afford my prescription. But for Medicare patients on Revlimid, the median out-of-pocket cost is $14,461 per year — that's over half their annual income.[5,6]

This week, I started taking a second generation version of that same drug. It has gone up in price by 65% over the past six years. My out-of-pocket cost for the first fill was $2,758 and I expect my total annual out of pocket to be more than $13,000 per year — just for that one drug.

Revlimid is an old drug — it was approved by the FDA in 2005 — and the principal reason it is so expensive is because its maker, Celgene, has gamed the system and refused to sell samples to generic companies trying to bring a competitor to market.[7, 8]

But Celgene isn't the only drug manufacturer gaming our patent system. Drug corporations often change drugs incrementally and patent the new product, which extends corporations' monopoly pricing power. For example, a company might move from a tablet to a capsule and apply for a new patent. Patents should not be issued for drugs that are not inventive. And gaming of the system to extend patents and block competition should not be permitted under U.S. law.

Here's how product hopping impacts patients.

Janice is from California. Her son was struggling to recover from opioid use disorder and needed Suboxone, a drug that has been subject to product hopping. She paid for it, but the roughly $60 per week was a strain on her family's budget. She was forced to take out a loan and depleted all of her savings to pay for this medication. "This medicine has been extremely helpful for him," she says. "Addiction is a deadly disease and I'm glad there is a medication that helps to combat it, but it shouldn't be this costly."

She is right.

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[4] https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-september-2019/

[5] https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-tables/

[6] https://www.kff.org/report-section/medicare-beneficiaries-out-of-pocket-health-care-spending-as-a-share-of-income-now-and-projections-for-the-future-report/

[7] https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/889/revlimid-lenalidomide

[8] https://www.bloomberg.com/news/articles/2018-05-17/u-s-names-drugmakers-gaming-safety-system-to-shield-profits

Janice's story highlights a drug that has been subject to one of the most egregious examples of product hopping. When faced with patent expiration and generic competition on its blockbuster drug, Reckitt Benckiser switched from a Suboxone tablet to a film that dissolves under the tongue. The company released the film shortly before losing the monopoly on the Suboxone tablet, and then made every effort to switch patients to the film by raising the price of the tablet and flooding doctors' offices with samples of the new version.[9] Then, citing safety claims later found to be fraudulent, they discontinued the older version, forcing all Suboxone patients onto their new patent-protected version.[10] Reckitt Benckiser undertook this scheme while tens of thousands of Americans were dying annually from misuse and overdoses of opioids.[11]

But it's not just product hopping on drugs for opioid use disorder or REMS abuses for cancer drugs. Other abuses of our system, like patent thickets, sham citizen petitions, and pay-for-delay deals serve to block competition and keep prices high.

Drug prices are bankrupting us. And as people are rationing drugs and skipping them altogether, high prices can literally kill us.

Section III. It's Not About Innovation

The good news is, we can fix this. Despite what drug companies tell us, sky-high drug prices are not about innovation.

Pharma's argument seems to make sense on its face: research and development are expensive.

This claim mangles the facts.

There is no direct correlation between R&D costs and the price of a drug. As policy expert Avik Roy wrote: "Proponents of high U.S. drug prices argue that high prices are necessary to support pharmaceutical innovation. But, with a modicum of scrutiny, the fatal flaws in this argument become immediately apparent."[12]

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[9] https://www.thedailybeast.com/suboxone-creators-shocking-scheme-to-profit-off-of-heroin-addicts

[10] https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc

[11] https://www.cdc.gov/drugoverdose/data/statedeaths.html#targetText=70%2C237%20drug%20overdose%20deaths%20occurred,driver%20of%20drug%20overdose%20deaths.

[12] https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08

Dr. Peter Bach, of Memorial Sloan Kettering Cancer Center, and his colleagues also examined this issue in depth. Their findings "counter the claim that the higher prices paid by U.S. patients and taxpayers are necessary to fund research and development."[13]

Right now, drug companies make enormous profits — roughly two to three times the average of the S&P 500 — and spend most of it on expenses outside of R&D.[14] Nine out of 10 big pharmaceutical companies spend more on marketing, sales, and overhead than on research.[15]

From 2013 to 2017, the five largest U.S.-based drug companies spent less than one-fifth of revenue on research and development on average.[16] The same companies — Johnson & Johnson, Pfizer, Merck, AbbVie, and Amgen — spent about 70% more on sales, marketing, and administrative expenses than R&D in this same timeframe.[17]

We must fuel innovation. And yet, I can also tell you that the risk companies cite is not the reality. That money invested in research isn't coming from companies alone; it's coming from the American people.

U.S. taxpayers foot a huge and critical portion of the bill to develop new drugs. Based on a survey of PhRMA's own member companies, one out of every three dollars spent on drug research comes from American taxpayers.[18,19] Every single drug approved by the FDA from 2010-2016 was based on science funded by taxpayers through the NIH.[20]

Under our current system, taxpayers are forced to pay three times for breakthrough treatments. First as taxpayers investing in research at the NIH, second as patients at the pharmacy counter, and a third time through tax dollars that support America's largest health insurance programs — Medicare and Medicaid.

The National Academies of Sciences, Engineering, and Medicine recently hosted a workshop where experts discussed multiple ways to ensure our investment in NIH balances critical innovation with essential access and affordability. Some of the approaches discussed include:

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13 https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/

14 https://www.gao.gov/products/GAO-18-40

15 https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172

16 Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

17 Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

18 https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill

19 https://www.phrma.org/advocacy/research-development

20 https://www.pnas.org/content/115/10/2329

- NIH could reinstate its reasonable pricing provision in Cooperative Research and Development Agreements (CRADA) and Exclusive Licensing Agreements. This provision was removed by the NIH in 1995.[21]
- Congress could create an outside entity to support NIH and ensure price is addressed when technology is transferred from the NIH to the private sector.

A specific legislative proposal to address these issues is the bipartisan WePAID Act introduced in the Senate by Senators Chris Van Hollen (D-MD) and Rick Scott (R-FL). The bill would ensure that drug companies set a reasonable price and limit annual price increases in cases where taxpayers contributed to the development of a new drug.

Yes, drug companies should make money when they create innovative drugs. But we are way out of balance, and it's costing us all — in bankruptcies, health outcomes, and lives.

The fact is, there is one key reason drug companies charge such high prices: Because they can.

Section IV. Immediate Legislative Solutions

Fortunately, there are three steps our nation could take today to rebalance the actual risk of innovation with a fair price for patients: reform patent law, end the days of monopoly pricing power without taxpayer negotiations, and force transparency from drug middlemen.

Let's start with patent law.

When a company brings an innovative drug to market, it should receive a fair return for their risk and investment. But drug manufacturers are abusing America's patent and exclusivity system to prevent free-market competition and block affordable generic and biosimilar drugs from coming to market.

Between 2005 and 2015, at least 74% of the new drug patents issued were for drugs already on the market.[22]

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.[23]

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[21] https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html

[22] https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows

[23] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567

These tactics have led to longer exclusivity than our laws intended. The median length of post-approval market exclusivity for small-molecule drugs was not five years or even the seven years allowed for orphan drugs. It was 12.5 years.[24]

Today, I will focus on one specific strategy used to extend monopolies — product hopping. One of the best definitions of product hopping I have read is this:

> "Product hopping, also called 'forced switching' or 'evergreening,' involves a brand-name company switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantage. The newer version, for example, could have a slightly different tablet or capsule dose or a slow-release formulation (given once a day rather than twice daily). In conjunction with this change, the company spends heavily to convince doctors and/or patients to switch to the new drug and may even withdraw the (often profitable) older drug from the market before its patent expiration date. When the generic version of the drug becomes available, pharmacists cannot substitute it for the new (branded) version because state laws allow drug substitution only if the dosage strength and other characteristics remain the same."[25]

As we approach product hopping from a patient perspective, *the key challenge is to act in a manner that encourages and protects real innovation that delivers meaningful clinical and therapeutic benefits while stopping product hops designed only to thwart competition and keep prices high.*

We support product evolution that improves effectiveness or reduces toxicities of a drug. I take a drug that causes painful peripheral neuropathy — loss of feeling in my feet. If a reformulated drug were to reduce this type of side effect, it would be a positive and innovative change for patients and could merit a patent extension when, for example, the mechanism meets the standards of non-obviousness required for a new patent.

But when drug companies offer a new product that does not provide clinical or therapeutic benefit, there should be no extended patent life.

After a drug company makes incremental or non-innovative changes, it often performs a "soft switch" or a "hard switch" to transfer its market share from the old drug to the new.

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[24] FN-*Wang B, Liu J, Kesselheim AS. Variations in time of market exclusivity among top-selling prescription drugs in the United States. JAMA Internal Medicine 2015;175(4):635-637.*

[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/

A soft switch occurs when a drug company aggressively markets the new drug to physicians and patients; it is often accompanied by a price hike in the older drug. A hard switch occurs when a manufacturer stops selling the older version of the drug altogether.

Under both instances, drug makers often flood doctors' offices with free samples of the "new" version for which there isn't a ready generic equivalent.

One reason soft and hard switches are effective in maintaining a drug company's monopoly over a drug can be found in state substitution laws — which are essential policies to encourage and speed market uptake and penetration for generics.

> "States have also made it easier for generics to reach the market through their enactment of drug product selection (DPS) laws. Such laws, in effect in all fifty states today, are designed to lower consumer prices. The laws allow (and in some cases require) pharmacists—absent a doctor's contrary instructions—to fill prescriptions for brand-name drugs with generic versions."[26]

In the soft switch, the promotion is aimed at getting consumers to request and physicians to write prescriptions for the new version of the drug, thus limiting and/or preventing substitution. In the hard switch, given the importance of substitution laws in driving up generic market share, the new generic is doomed because there is no longer a brand drug for which to substitute.

Clearly, these practices are designed to circumvent the intent of Hatch-Waxman and state substitution laws. How does this play out for patients? Simply stated: We have less choice and pay higher prices.

Two drugs been involved in high-profile product hopping cases are Suboxone and Tricor. Here's what patients have told us about both.

> *Samantha from West Virginia wrote: "I have been in recovery for over ten years now. The cost of Suboxone is outrageous — especially since, from the time I began taking it until now, the price is still as high or higher. It's ridiculous! It's easier for people to misuse narcotics (the cost is less). The cost for Suboxone is about $800 [for a 90-day supply]."*
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> *Beatel from Minnesota told us: "When I changed to Medicare at 65, my price for 40mg of Tricor went to $1,800/month. The pharmacist whispered to me, 'If the doctor changed the order to 160mg tabs and I broke it in half for the 80mg dose, it would cost me $40.'*

[26] https://scholarship.law.nd.edu/ndlr/vol92/iss1/4/

The drug company still had the patent on the 40mg tab. The patent for the 160mg tab had expired…same drug."

The encouraging news is that multiple bills are presently making their way through Congress that would help address product hopping abuses:

- *REMEDY Act (S. 1209/H.R. 3812):* This bill is led by Senators Durbin (D-IL) and Cassidy (R-LA) on the Senate side and Representatives McKinley (WV-01) and Welch (VT-At Large) on the House side. REMEDY allows generic manufacturers to enter the market more easily once the substantive patent and all exclusivities have expired and reduces incentives to litigate patent infringement on non-substantive patents. This would allow generic manufacturers to bring drugs to market sooner.

- *Terminating the Extension of Rights Misappropriated (TERM) Act of 2019 (H.R. 3199):* This bill, led by Representatives Jeffries (NY-08) and Collins (GA-09), would nullify all patents for a drug once the first patent expires, unless the drug maker can demonstrate with a preponderance of evidence that a new patent covers an invention that is "patentably distinct". This bill would limit the ability of pharmaceutical companies to extend their monopoly exclusivities by product hopping.

- *Affordable Prescriptions for Patients Act (S.1416)* This bill is led by Senators Cornyn (R-TX) and Blumenthal (D-CT), and establishes product hopping as an anti-competitive behavior in violation of antitrust law. Under the bill, product hopping is defined as when a manufacturer obtains approval of an application for a change, modification, or reformulation of an already existing and approved drug that makes generics that were previously substitutable for the drug no longer substitutable. Exceptions to the bill are generally any evidence that the competitive benefits outweigh the anticompetitive.

Members of this committee are supportive of numerous other bipartisan bills to address patent abuses and anti-competitive industry practices. I thank Committee members for their work. We have lent our support to the following bipartisan bills making their way through the House and Senate to address these abuses:

- **Pay-for-delay Deals:** Brand name drug companies pay off generic companies that plan to bring a competitor to market. In exchange for this payment (or something of value that could be another commercial consideration), the generic manufacturer delays its product's entry into the market. This practice is addressed by H.R. 2375, the *Preserve Access to Affordable Generics and Biosimilars Act,* sponsored by Representatives Nadler (NY-10) and Collins (GA-09).

- **REMS abuses:** Brand drug companies use a safety program called Risk Evaluation and Mitigation Strategies (REMS) as a pretext for not selling drug samples to generic companies, which need the brand product in order to develop an equivalent and lower-priced competitor. The U.S. government could save $3.9 billion[27] by stopping this abuse, which the FDA has called "unfair and exploitative."[28] The bipartisan CREATES Act (H.R. 965) tackles this issue by providing an avenue for generic companies to sue brand name companies for samples. In the House, CREATES is led by Representatives Cicilline (RI-01), Sensenbrenner (WI-05), Nadler (NY-10), Collins (GA-09), Welch (VT-At Large), and McKinley (WV-01).

- **Patent-thickets:** Brand drug companies often file dozens of new patents on old drugs in order to force a generic company to file suit against each of them, delaying a generic competitor from coming to market. For example, AbbVie secured more than 100 patents on Humira and is currently blocking a competitor in the U.S.[29] The *Affordable Prescriptions for Patients Act (S.1416),* sponsored by Senators Cornyn (R-TX) and Blumenthal (D-CT) provides authority to challenge patent thicketing behavior as anti-competitive.

- **Sham citizen petitions:** Brand-name drug makers were behind 92% of all citizen petitions filed between 2011 and 2015 — all aimed at blocking cheaper generic drugs. The FDA threw out nine of every 10 of those petitions.[30] Congress should stop the use of sham citizen petitions. Both the *Ensuring Timely Access to Generics Act of 2019* (H.R. 2455), sponsored by Representatives Joyce (PA-13) and Brindisi (NY-22), and *Stop STALLING Act* (H.R. 2374), led by Representative Jeffries (NY-08) and others, add scrutiny and accountability to the citizen petition process.

- **Transparency and price hikes:** Drug prices cannot be properly addressed without achieving transparency on the part of pharmaceutical manufacturers. The *Fair Drug Pricing Act (H.R. 2296)* requires manufacturers to report and justify certain price hikes. This bill, sponsored by Representatives Schakowsky (IL-09) and Rooney (FL-19), passed out of House Energy and Commerce Committee as part of the *METRIC Act*.

Next, we need Medicare price negotiations.

Over the past five years, AbbVie, the company that makes the top selling drug in the world, Humira, has more than doubled the price here in the United States. But in Europe, Abbvie sells

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[27] https://www.cbo.gov/publication/54479

[28] https://www.fda.gov/news-events/speeches-fda-officials/remarks-ftc-workshop-understanding-competition-prescription-drug-markets-entry-and-supply-chain

[29] https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug

[30] https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1956&context=aulr

the exact same drug for 80% less.[31] On average, Americans pay twice as much for prescription drugs as other nations.[32]

Why does the rest of the world get affordable drugs while Americans pay outrageous prices?

One big reason is that other countries negotiate directly with drug companies. We should, too. Given the prices we pay, it is clear that relying on pharmacy benefit managers to negotiate is not working. We know that not only from the experience of other nations, but also from the Veterans Administration (VA). The VA negotiates and Medicare Part D could have saved $14.4 billion in 2016 alone by negotiating as the VA did.[33]

Medicare negotiations can take several approaches; the VA approach is just one. The framework recently reported on from leadership in the House of Representatives would ensure that Americans benefit from lower drug prices whether covered by a government plan or private insurance. Importantly, it incorporates bipartisan elements like international reference pricing and inflation caps. We look forward to reviewing the bill when it is introduced.

Finally, we need more transparency around Pharmacy Benefit Managers (PBMs). They are the middlemen between insurance companies and manufacturers. These groups cut secret rebate deals that determine how much insured patients pay — but there's no transparency in this process.

As a patient, I cannot know if the preferred drug on a formulary is the most effective drug, the least expensive among equally effective options, or the drug for which the PBM received the biggest rebate. That is unacceptable.

Moreover, rebates are sometimes used to stymie competition. Professor Robin Feldman explains "the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs."[34] Lower-priced alternatives may be unable to gain traction in the market because of a huge, legal kickback given for use of the more expensive brand — costing patients, consumers and taxpayers.
Secret rebates are bad policy. This is economics 101: Competition — the free market — can't work effectively without transparency.

Section V. Conclusion

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[31] https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html

[32] https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

[33] https://www.statnews.com/pharmalot/2019/01/14/medicare-drug-prices-veterans-affairs/

[34] https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm_term=.f9e74687f9af

Right now, Big Pharma wants us to ask this question: What are we willing to pay to save a life?

And that's easy. When it's your child's lungs on the line, when it's your wife's diabetes, your husband's cancer, the answer is "anything." Yes, we will empty our 401ks; yes, we will take out another mortgage on our home; yes, we will give every precious thing we have, every cent, for one more year. One more day.

The chance to walk my daughter down the aisle? The chance to meet my grandkids — to watch them grow up? There is no amount I wouldn't give for that.

But that's the wrong question. We should be asking: *What is the right amount of money that drug companies should make on these drugs?*

With hundreds of clinical trials underway for new gene therapies that are currently priced from a half-million to more than two million dollars, we cannot agree to any price a drug company wants to charge. Neither American families nor our health care system can afford that.

Through our organization, I met a woman named Ruth Rinehart. Ruth has primary immune deficiency, and her treatments cost around $52,000 per year. After working as a nurse for 30 years, she retired; and when her husband lost his job, they could no longer afford her treatments. They were forced to file for bankruptcy and eventually lost their home. Today, Ruth and her husband are in debt, living paycheck to paycheck, and she's back at work.

I feel incredibly grateful to spend my retirement fighting so that people like Ruth can one day enjoy theirs.

Because no one should have to choose between their health and their home.

All of you hold the power to fix this broken system. My request to you: deliver for the American people. It's time to enact reforms. It's time to stop these blatant abuses that keep drug prices high. Keep a focus on patients. And keep working together to address this urgent issue.

Cancer broke my back, but it stiffened my spine. I believe this is a problem that we can solve. That we must solve. And with bipartisan support, we will solve. Thank you for your time.