PATIENTS FOR AFFORDABLE DRUGS NOW™

Statement by David Mitchell
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to the

U.S. House of Representatives Committee on Oversight and Reform

on

"Examining the Actions of Drug Companies in Raising Prescription Drug Prices"
Tuesday, January 29, 2019

Chairman Cummings, Ranking Member Jordan, and members of the House Committee on Oversight and Reform,

Cancer literally broke my back. It also taught me a powerful lesson: The prescription drug pricing system in the U.S. is rigged against patients.

I have an incurable blood cancer called multiple myeloma. I was diagnosed when the cancer ate through one of my vertebra and I couldn't move. Every four weeks, I have a cocktail of drugs infused into my body. It takes five hours, and the price is more than $325,000 a year.

I'm grateful for these drugs. And I'm a huge supporter of research and innovation. If drug companies don't invent new drugs, I will die sooner than I hope.

The need for innovation is not theoretical for me—it's life and death.

My experience taught me one simple fact: Drugs don't work if people can't afford them.

That's why my wife and I launched Patients For Affordable Drugs Now. We are the only national patient organization focused exclusively on policies to lower drug prices. We are bipartisan and independent. We don't accept funding from anyone who profits from the development or distribution of prescription drugs.

We hear every day from patients suffering under the high cost of prescription drugs — cutting pills in half, choosing between groceries and medication, and simply going without. Here are just three of those stories:

Ruth Rinehart from Tampa, Florida has Primary Immune Deficiency. She has received antibody replacement every three weeks for the last two decades. The cost of the infusions vary between $3,000 to $4,000 each time. These drug costs have been crippling — when her husband lost his job in the recession, Ruth's family lost her home and had to file for bankruptcy because they couldn't afford her medications. So instead of having a retirement savings, they were living month to month on Social Security. Now, at age 70, Ruth is back at work just to afford her medications.

Pam Holt from South Bend, Indiana is a widow and a retired teacher. She is currently living with blood cancer. In order to keep her cancer at bay, she takes Revlimid, a Celgene drug. Her copay for Revlimid is $640 per month. Over the course of her treatment, she's taken on debt in order to afford the drugs. She had to refinance her home recently to retire that debt—the house was three years from being paid off.

Bob Keller from Parsippany, New Jersey was forced to retire after complications from diabetes led to a kidney transplant. He wants his 65-year-old wife to be able to retire too, but the brunt of his drug costs rest on her. So she is still working with no retirement in sight. She can't stop working because if the Keller's were to use Medicare, Bob's diabetes medication could cost up to $1,800 per month.

In all of the stories we hear, there is one overarching sentiment—people feel their government has let them down.

Addressing drug prices is popular. A recent Harvard/Politico poll, showed that 80 percent of Americans people say that Congress's top priority should be action to lower drug prices. Republicans and Democrats chose it as their top choice of issues for Congress to tackle.

How Congress can address drug prices

We are grateful Congress is shining a spotlight on drug pricing. The stage is set for the 116th Congress to take meaningful action on drug prices and bring relief to patients.

When we look at legislative priorities, we divide them into two categories: 1) legislation that we believe can pass in this Congress and be signed into law and 2) legislation that lays the groundwork for enactment in the next Congress.

Legislation that can pass in this Congress

First, patent reform is essential for long-term systemic change — and it enjoys bipartisan support. Drug manufacturers abuse America's patent system to prevent free-market competition and block affordable generic drugs from coming to market. Patent reform would allow the Hatch-Waxman framework to work the way it is intended. Drug manufacturers' current patent gaming tactics include: REMS abuse, pay-for-delay deals, sham patent transfers, building of patent thickets, evergreening, and sham citizen petitions. We are supportive of the following legislation to address these abuses:

- **Deals-For-Delay:** Brand name drug companies pay off generic companies that plan to bring a competitor to market. In exchange for this payment, the generic manufacturer delays its product's entry into the market.
    - *Recent legislation: S.64 Preserve Access to Affordable Generics and Biosimilars Act.* This bill would would limit deals in which brand and generic drug manufacturers use anti-competitive pay-off agreements to delay cheaper generic and biosimilar drugs from reaching patients.
    - *Recent legislation: S.2476 Expanding Access to Low Cost Generic Drugs Act.* This bill would give the Food and Drug Administration the ability remove the 180-day generic drug exclusivity period from a generic company that enters into a pay-for-delay deal with a brand-name drug manufacturer.
- **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. could save $3.9 billion by stopping this abuse, which the FDA has called "unfair and exploitive."
    - *Recent legislation: S.194/H.R.2212 CREATES Act, H.R.2051 FAST Generics Act.* These bills address delay tactics that are used by brand drug manufacturers to block lower-priced generic drugs.
- **Evergreening:** Drug corporations change drugs incrementally and patent the new product, which extends a corporations' monopoly pricing power. For example, a company might move from a tablet to a capsule and apply for a new patent. This gaming of the system should not be permitted.
- **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. A recent report found that 75 percent of patents are filed on old drugs instead of new, innovative drugs that improve people's lives.
- **Sham Citizen petitions:** Brand-name drug makers were behind 92 percent of all citizen petitions filed between 2011 and 2015 — all aimed at blocking cheaper generic drugs. The FDA denied more than nine of every 10 those petitions. Congress should stop the use of sham citizen petitions.
- **Renting sovereign immunity:** One brand name company sold the patent for its drug to an American Indian tribe, which has sovereign immunity in some legal proceedings. The move was designed to prevent drug patent review and block generic competition. So far, courts have not allowed this practice to stand, but appeals continue. Congress should outlaw this tactic.
    - *Recent legislation: S.2514 PACED Act.* This legislation would address the sale of patents to sovereign entities to avoid competition from generic drugs.

Second, we support legislation that demands transparency from the middlemen in the drug supply chain and believe it has a real chance to become law during the 116th Congress. We are supportive of legislation that would shed light on pharmaceutical manufacturers as well pharmacy benefit managers. Increased transparency will allow us to gain insight into how pharmacy benefit managers function. Only then can we properly address drug pricing throughout the drug distribution pipeline.

- **PBM transparency**: Pharmacy Benefit Managers — the drug middlemen who are supposed to operate on behalf of patients — are a black box. Every PBM receives rebates and other forms of payments from drug manufacturers. Each PBM decides what product lands on its list of approved drugs. The public doesn't know how much — if any — of the benefit of rebates reaches patients and consumers, or the extent to which PBM practices keep prices unnecessarily high. It's long past time for rebates to go away and to transition to a system of transparent net prices.
    - *Recent legislation: S.637 Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act.* This bill would require the disclosure of rebate arrangements between PBMs and insurance plans.

Third, protect patients from price gouging.

- **Price Gouging**: Drug corporations should be required to disclose price increases above a certain amount and the inputs behind them. Such required reporting should include: research and development costs, cost of production, marketing and advertising costs, and yearly profit on the drug.
    - *Recent legislation: S.1131, H.R.2439* F*air Accountability and Innovative Research Drug Pricing Act.* This bill would require pharmaceutical manufacturers to report information related to drug pricing when prices increase by 10 percent over 12 months or 25 percent over 36 months.
    - *Recent legislation: S.3754 CURE High Drug Prices Act.* This legislation would identify drugs that experience price spikes of ten percent or more over 12 months, 20 percent or more over 26 months, or 30 percent over 60 months and allow the Secretary of Health and Human Services to determine whether the price hikes were price gouging.
    - *Recent legislation: S.1348 Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act.* This bill would would require drug manufacturers to report justifications for significant increases in the list price if a) the drug is at least $10 per dose and had a price increase of at least 300 percent over 5 years or 100 percent over 1 year; and b) The drug represents the top 50th percentile of net drug spending in the Medicare or Medicaid programs and had a price increase of at least 50 percent over 5 years or 15 percent over 1 year.

Legislation to lay the groundwork for next Congress

Drug companies understand that America is the only country in the world that doesn't negotiate with manufacturers over the price of drugs purchased by taxpayers. Negotiating for lower prices is the definition of capitalism. The U.S. Department of Defense negotiates with Lockheed Martin over the price of jets. The government's failure to negotiate on drug prices hurts patients and taxpayers. According to a recent study in JAMA, Medicare Part D could have saved $14.4 billion in 2016 alone by negotiating as the Department of Veterans Affairs does.

There are several models of Medicare negotiation the government could use. The following is a brief overview:

- **Removal of the non-interference clause (bipartisan support):**

    - *Recent legislation:* H.R. 275 *Medicare Prescription Drug Price Negotiation Act*
- **Formularies:**
    - *Recent legislation:* S.99 *The Medicare Drug Price Negotiation Act*
- **Binding Arbitration:**
    - *Recent proposal:* If an agreement on the price of a drug can't be reached, the drug company and government enter into arbitration. If the company won't submit to arbitration, the pharmaceutical manufacturer should be barred from selling its products through Medicare and Medicaid. Alternatively, Hatch-Waxman could be amended to state that grants of exclusivity are conditioned on agreement to abide by binding arbitration in Medicare.
- **Compulsory Licensing:**
    - *Recent legislation: H.R.6505 Medicare Negotiation and Competitive Licensing Act*
- **International Pricing Index Model (bipartisan support):**
    - *Recent proposed demonstration by the Department of Health and Human Services*: Americans pay up to three times more than other countries for prescription drugs. The Department of Health and Human Services' plan to use an International Pricing Index to bring U.S. drug prices for the most expensive infused drugs more in line with other wealthy countries has merit. Ultimately, while International Reference Pricing can be a step toward lower prices, we continue to believe a better mechanism would be direct negotiations by Medicare given the U.S. government's purchasing power.

Lastly, we must ensure that U.S. taxpayers are getting a good deal on the drugs we help invent. As the U.S. Department of Commerce said in December 2018, "The U.S. innovation system is substantially fueled by the discoveries and inventions arising from federally funded R&D at the nation's universities, research institutes, and Federal Laboratories."

According to the National Academy of Sciences, all 210 drugs approved by the FDA from 2010 to 2016 were based on research funded by taxpayers through the NIH. Effectively, taxpayers often de-risk the research and development enterprise. Once a drug shows promise, pharmaceutical manufacturers swoop in to acquire the intellectual property and bring the drug to market for hundreds of thousands of dollars.

We believe this must be addressed. Currently, the National Academy of Medicine is examining the pricing practices around drugs developed with NIH-funded research — we encourage Congress to investigate this phenomenon and develop solutions to address it.

CONCLUSION

Cancer broke my back, but it stiffened my spine. Together, we can stop abuses by the drug industry. Unchecked, Big Pharma will continue to hold patients' lives and livelihoods hostage. Congress needs to let drug companies know that its abuses won't stand any longer.

We are very grateful to the Committee for its leadership in the fight to lower prices of prescription drugs. We look forward to supporting your work in the months ahead to bring relief to patients like Ruth, Pam, and Bob.