

Questions for the Record from Senator Chuck Grassley of Iowa

“Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition”

May 7, 2019

Questions for Mr. Baker

USPTO Director Iancu says that the U.S. Patent Office does not grant patents for “tweaks” or minor improvements to inventions. Do you agree? Please explain. If you believe that this is an issue, what action would you recommend Congress take to ensure that follow on patents for drug improvements are only granted for true innovations?

Questions for Mr. Mitchell

USPTO Director Iancu says that the U.S. Patent Office does not grant patents for “tweaks” or minor improvements to inventions. Do you agree? Please explain. If you believe that this is an issue, what action would you recommend Congress take to ensure that follow on patents for drug improvements are only granted for true innovations?

Patients across the country are not able to get the lifesaving medicines they need. Drugmakers have engaged in rampant over-patenting to extend monopolies far longer than our country's laws intended: 20 years.

Congress must address the problem of high drug prices at their root: a patent system that is being gamed by pharma companies through a strategy called "evergreening." Drugmakers today are extending their patent monopolies by filing patents on minor changes to an existing drug — a capsule instead of a tablet, for example. And it often works. For instance, the company that makes the best selling drug in America, Humira, has filed for 247 patents. That's an attempted 39 years of patent protection, during which time they could charge prices at whim. Revlimid, a drug that I took myself for more than five years, has seen 106 patents filed, which is an attempted 40 years of protection. It flies in the face of any rational logic that there are over 100 inventions for each medicine in America today, and yet the 12 best selling drugs in America have on average 125 patent applications filed per medicine.

We believe a comprehensive set of legal and policy changes are required to close these loopholes and foster competition in the market. Foremost amongst our recommendations is to raise the bar for what is inventive, which will stop the evergreening practices, and allow patients to get the affordable medicines that our lives depend upon. As a first step Congress should hold investigations into the U.S. patent system and the practices at the US Patent and Trademark Office to determine how best to ensure patents are issued for inventions that improve the lives of patients and all Americans.

Questions for Mr. Stansel

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Questions for Professor Carrier

Do you think the pharmacy benefit manager (PBM) industry is competitive? Do new competitors face high barriers to entry in the PBM marketplace?

Do you think recent consolidations between PBMs and insurers (or other participants in the pharmaceutical supply chain) result in lower drug costs to the government (as a payer) and the consumer? Why or why not?

Do you view the practice of so-called “rebate traps” or “rebate walls” as harmful to patients’ access to quality, lower cost medicine? Why or why not? And should Congress be examining ways to address this issue?

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Questions for Professor Olson

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Questions for the Record for Mr. David Mitchell
Senate Committee on the Judiciary
Hearing on “Intellectual Property and the Price of Prescription Drugs: Balancing
Innovation and Competition”
May 7, 2019

QUESTIONS FROM SENATOR BLUMENTHAL

1. The CURE High Drug Prices Act would require pharmaceutical companies to justify to the Department of Health and Human Services any drug price increase over 10% in one year, 20% over three years, and 30% over five years and provide the federal government the power to block an unjustified price gouging.

a. What impact does excessive price hikes have on consumers?

We have collected more than 20,000 stories from patients and their families all over the US. Because of excessive price hikes, they are cutting pills in half, skipping doses, choosing between buy food and paying for their drugs, going into debt. The fact is that high prices are leading to rationing of medicines that keep people alive or help manage difficult chronic conditions. Nearly eighty percent of Americans say drug prices are unreasonable.¹ One-quarter of Americans say it is difficult to afford the cost of their prescription drugs.²

b. Do you believe that the CURE High Drug Prices Act would be helpful in quelling high drug costs and increasing transparency?

Yes. Patients For Affordable Drugs supports the CURE High Drug Prices Act.

¹ https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/?utm_source=STAT+Newsletters&utm_campaign=c16cf09325-MR_COPY_03&utm_medium=email&utm_term=0_8cab1d7961-c16cf09325-150805841

² <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>

David Mitchell
President and Founder
Patients for Affordable Drugs
Questions for the Record
Submitted May 14, 2019

QUESTIONS FROM SENATOR BOOKER

1. During the hearing, you briefly discussed drug prices in other countries, and you noted that part of the reason the United States often pays significantly more for the same drugs is that we do not utilize tools, like negotiation, that would ensure Americans are getting a “fair shake.”

- a. What other tools could Congress or the Administration use to ensure that Americans are paying a fair price for prescription drugs, relative to our peer countries?

Direct negotiation by Medicare is the most important tool we should be using. Another approach to ensure Americans get a fair shake would be to use international reference pricing. Right now Americans pay 2-3 times what other wealthy nations pay for the same drugs.¹ We could use a pricing index based on prices paid in other developed countries to establish appropriate prices for the US.

The fact is that we are establishing prices Medicare pays for some drugs right now based on average sales prices. Medicare Part B drugs are reimbursed based on the Average Sales Price in the US. That is a very high price—roughly 80 percent higher than other wealthy countries.² We could use an average global sales price to establish reimbursement rates for these drugs which would ensure prices in the US are in line with prices around the world.

- b. Would you support legislation like the Affordable and Safe Prescription Drug Act, a bill I co-wrote with Senators Sanders and Casey to allow pharmacies, individuals, and others to safely import prescription drug medications from Canada and, after a time, other OECD countries? Why or why not?

Patients are importing medicines from outside the US right now because they cannot afford the prices in this country. Our preferred solution is to fix our pricing problem in this country, and not rely on importation. Americans should be able to purchase affordable drugs they need in the US. In the absence of reforms to ensure affordability in the US, safe importation can help provide relief for patients and consumers and the bill referenced above would give Americans that option.

¹ <https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/?redirect=1>

² <https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs>