

PATIENTS FOR AFFORDABLE DRUGS™

Statement of David E. Mitchell

Founder, Patients For Affordable Drugs

before the

**U.S. House of Representatives Committee on Oversight and Government Reform,
Subcommittee on Health Care, Benefits, and Administrative Rules**

on

**“Examining the Impact of Voluntary Restricted Distribution Systems in the
Pharmaceutical Supply Chain”**

March 22, 2017

Mr. Chairman, Members of the Committee, thank you for inviting me here today.

I am David Mitchell. I am the founder of Patients For Affordable Drugs, a national patient organization focused exclusively on policies to lower prescription drug prices. To maintain our independence, we do not accept funding from any organizations that profit from the development or distribution of prescription drugs. We are about patients first, last, and always.

My wife is a cancer survivor. She and I contributed seed money to the effort. And we received a grant from the Laura and John Arnold Foundation. I retired to devote myself to this cause, and I work for free.

More importantly for the committee, I am a relapsed cancer patient with multiple myeloma—an incurable blood disease. Drugs are keeping me alive. And because my cancer finds its way around drugs, I need new ones. So the importance of innovative, affordable drugs is not theoretical for me—it’s life and death.

I hope to watch my youngest son graduate from high school in three years and to have one of my older kids give me a grandchild one day. I am *very grateful* for the drugs produced by the science and research sector in our country. But life-saving drugs must come at prices that don’t bankrupt patients and ruin the lives of people struggling to maintain their health.

Yesterday, I sat in an infusion room for almost five hours receiving a two drug combination that costs more than \$26,000 per month.

Prior to this drug regime, I was on Revlimid for five-and-a-half years, and I participated in Celgene’s Risk Evaluation and Mitigation program. I obtained my drugs only from specific

specialty pharmacies. Each month, I received counseling on the risks of the drug, and I participated in a survey designed to remind me of those risks—the most dangerous is birth defects if I impregnated a woman while taking Revlimid.

The counseling under the program consisted of a nurse reading a list of cautions to me. The survey was an automated phone call—press one for yes and two for no. The whole process took 5-10 minutes. It could have been easily duplicated by any generic manufacturer. It wasn't rocket science.

Of course, during this same period, Celgene was doing its best to delay generic versions of the drug by hiding behind its restricted distribution system and REMS—refusing to give samples to generic drug makers. Here's what that meant for me: My out-of-pocket cost for Revlimid went from \$42 a month in 2011 to \$250 a month by the time I had to stop taking it last year because of side effects. As you can see from the attached bill, the retail price for one four-week cycle of Revlimid is \$10,691—more than \$500 per capsule.

I am lucky. I had good employer-provided insurance. But Medicare beneficiaries aren't always so fortunate. The median out-of-pocket cost for a Medicare beneficiary taking Revlimid is \$11,500 per year. It is the most expensive Medicare drug.

Members of the committee, that's the impact of REMS abuse, and it's part of the problem with drug prices in America. Patients are forgoing their medications—they are spending their retirement funds and emptying their kids' college savings to afford drugs when a generic competitor sits around the corner.

In 2015, Celgene reported \$1.6 billion in profits. Revlimid accounted for 63 percent of its revenue. Revlimid is key to propping up its stock price.

It's clear to me that Celgene is gaming our system. It is using the bogus pretext of Risk Evaluation and Mitigation to unlawfully deny samples to generic manufacturers in order to prevent them from developing a cheaper alternative. It is ripping off patients and taxpayers while blocking market competition.

Let me make the comparison more stark: The median income of a Medicare beneficiary is about \$24,000 per year. The median out-of-pocket cost for Revlimid is \$11,500 per year. But the CEO of Celgene—Robert Hugin—was paid almost \$100 million dollars over three years. That is like a direct income transfer from the patient on Medicare to Mr. Hugin. It is just plain wrong. But they promoted him to Executive Chairman. Job well done.

We need to reform the law to stop these abuses. But speeding generics to market will only address a fraction of the problem of high drug prices.

The problem is that instead of a competitive free market for prescription drugs, we have a system of monopoly pricing by the drug companies enforced through government policy. We have pharmacy benefit manager middlemen who process \$323 billion in drugs each year—but who keep all their deals secret.

As President Trump has said—and 82% of Americans agree¹—it is time to allow Medicare to negotiate prices for drugs on an open market instead of allowing drug companies to act as monopolies. I also believe that requiring transparency into PBMs and into prices set when a drug is invented using taxpayer funding would go a long way toward making drugs more affordable. And we should set prices based on the value drugs deliver to patients.

Finally, as a patient completely dependent on innovation and new drugs for my survival, I know we can have innovation and new drugs while reducing prices. Drug corporations try to scare patients by saying that they must have high profits or they will stop investing in research. But independent analyses show that while drug companies spend at best a few pennies of every dollar of revenue on basic research, they spend 20-40 cents on marketing and advertising^{2,3}. The pharmaceutical industry is among the most profitable in the U.S. And health care and drug company executives are the highest compensated in the U.S. More than half of new drugs that come to market are based on breakthroughs in science paid for by taxpayers through NIH and academic medical centers.

Drug corporations can lower prices, pay for research and development and still provide a healthy return to shareholders. But it won't happen until we break the government enforced monopoly pricing power of the pharmaceutical industry, gain transparency on the part of PBMs, and restore competition in a free market that benefits patients, consumers and taxpayers.


I am extremely encouraged that members on both sides of the aisle are focused on drug prices. In my experience, the most enduring legislative successes in our country have come with bipartisan action. Thank you for your attention.

¹ Cubanski, Juliette, and Tricia Neuman. "Searching for Savings in Medicare Drug Price Negotiations." Kaiser Family Foundation, 23, Jan. 2017. Web. 20 Mar. 2017.

² Kantarjian, Hagop, and Vivian Ho. "The Harm of High Drug Prices." U.S. News & World Report, 12 Dec. 2016. Web. 20 Mar. 2017.

³ Yu, Nancy, Zachary Helms, and Peter Bach. "R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices." Health Affairs. N.p., 7 Mar. 2017. Web. 20 Mar. 2017.

Attachment 1:

<p style="text-align: center;">BriovaRx AL BriovaRx LLC 1100 LEE BRANCH LANE BIRMINGHAM, AL 352421507 (888)432-2797</p> <p>Rx: 19-7089348 Date: 01-18-2016 Drug Name: REVLIMID CAP 25MG CELGENE CORP</p> <p>GENERIC NAME: LENALIDOMIDE (LEN-a-LID-oh-mide)</p> <p>COMMON USES: This medicine is an immunomodulatory medicine used for treating anemia in patients who have certain types of myelodysplastic syndrome (MDS). It is also used along with dexamethasone to treat multiple myeloma (MM) in certain patients. It is also used to treat mantle cell lymphoma (MCL) in certain patients. It may also be used to treat other conditions as determined by your doctor.</p> <p>BEFORE USING THIS MEDICINE: WARNING: THIS MEDICINE MAY CAUSE SEVERE BIRTH DEFECTS OR DEATH OF THE FETUS IF USED DURING PREGNANCY. This medicine is similar to thalidomide, which causes life-threatening birth defects. FEMALES WHO ARE ABLE TO BECOME PREGNANT AND WHO TAKE THIS MEDICINE: must not become pregnant; must avoid sexual contact with men or use at least 2 forms of effective birth control for at least 4 weeks before starting this medicine, while taking this medicine, during breaks in treatment, and for at least 4 weeks after stopping this medicine; must have a negative pregnancy test 10 to 14 days before starting this medicine and every 2 to 4 weeks thereafter while using it. Women who experience abnormal menstrual bleeding, miss their menstrual period, become pregnant, or suspect for any reason they may be pregnant while taking this medicine must stop taking it and contact their doctor immediately. MEN WHO TAKE THIS MEDICINE must either avoid sexual contact with women who are pregnant or could become pregnant while taking this medicine and for at least 4 weeks after stopping this medicine; OR must use a latex or synthetic condom during sexual contact with women who are pregnant or could become pregnant for as long as they are taking this medicine, during breaks in treatment, and for at least 4 weeks after stopping this medicine, even if they have had a successful vasectomy. Men who have unprotected sexual contact with a woman who is pregnant or may become pregnant, or who thinks for any reason that their sexual partner may be pregnant should contact their doctor immediately. ALL PATIENTS: THE RISK OF BLOOD CLOTS (eg, in the veins or lungs, heart attack, stroke) may be increased with this medicine in certain patients. The risk may be higher in people who have multiple myeloma and take this medicine with dexamethasone. THIS MEDICINE MAY LOWER THE NUMBER OF WHITE BLOOD CELLS AND PLATELETS IN THE BLOOD. Call your doctor right away if you experience unusual bleeding or bruising, fever, chills, or sore throat. COMPLETE BLOOD COUNTS WILL BE DONE often while you are taking this medicine. Talk with your doctor. Sometimes blood transfusions and treatment with other medicines may be necessary. THIS MEDICINE CAN ONLY BE PRESCRIBED and dispensed through a special program called the Revlimid Risk Evaluation and Mitigation Strategy (REMS) program. Make sure you understand all warnings and instructions for using this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the-counter medicine that you are taking. ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking digoxin, erythropoietic agents, medicines that contain estrogens or progestins (eg, birth control pills), or medicines that may harm the liver (eg, acetaminophen, certain medicines for HIV infection). Ask your doctor if you are unsure if any of your medicines might harm the liver. Tell your doctor if you are taking any medicines that may increase the risk of bleeding or blood clots. Ask your doctor or pharmacist if you are not sure. DO NOT START OR STOP any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including a tumor, cancer, dialysis, kidney or liver problems, certain hereditary problems (eg, glucose intolerance), lactose intolerance, blood problems (eg, low white blood cells, low platelet counts), an infection, blood electrolyte problems, high blood pressure, high blood cholesterol, a history of blood clots or heart problems (eg, irregular heartbeat, heart attack), or allergies. Tell your doctor if you smoke. USE OF THIS MEDICINE IS NOT RECOMMENDED if you are breast-feeding, or are pregnant, planning to become pregnant, or become pregnant during treatment. Contact your doctor or pharmacist if you have any questions or concerns about using this medicine.</p> <p>HOW TO USE THIS MEDICINE: Follow the directions for taking this medicine provided by your doctor. This medicine comes with a MEDICATION GUIDE approved by the U.S. Food and Drug Administration. Read it carefully each time you refill this medicine. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine. TAKE THIS MEDICINE by mouth with or without food. SWALLOW THIS MEDICINE WHOLE with water. Do not break, crush, chew, or open before swallowing. DO NOT</p>	<p style="text-align: center;">RECEIPT</p> <p>BriovaRx AL BriovaRx LLC (888)432-2797 1100 LEE BRANCH LANE BIRMINGHAM, AL 35242150</p> <p>DAVID MITCHELL 11505 MORNING RIDE D POTOMAC, MD 20854</p> <p>(202)309-1994 05-04-1950 Rx# 19-7089348 01-18-2016 THAMBI, PAUL 9707 MEDICAL CENTER DRIVE SUITE 300 ROCKVILLE, MD 20850</p> <p>REVLIMID CAP 25MG CELGENE CORP Generic Name: Lenalidomide Cap 25 MG 59572-0425-21 Qty: 21 Refills: 0 Rx Price: \$10,691.63 IRX Ins Payable: 10441.63 Copay: \$250.00</p>  <p style="text-align: center;">THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE. RECEIPT</p> <p>BriovaRx AL BriovaRx LLC (888)432-2797 1100 LEE BRANCH LANE BIRMINGHAM, AL 35242150</p> <p>DAVID MITCHELL 11505 MORNING RIDE D POTOMAC, MD 20854</p> <p>(202)309-1994 05-04-1950 Rx# 19-7089348 01-18-2016 THAMBI, PAUL 9707 MEDICAL CENTER DRIVE SUITE 300 ROCKVILLE, MD 20850</p> <p>REVLIMID CAP 25MG CELGENE CORP Generic Name: Lenalidomide Cap 25 MG 59572-0425-21 Qty: 21 Refills: 0 Rx Price: \$10,691.63 IRX Ins Payable: 10441.63 Copay: \$250.00</p> <p style="text-align: center;">THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE. RECEIPT</p>
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