Ellsworth Area Chamber of Commerce
Sen. Susan M. Collins
June 1, 2016

Thank you, Ed. It is a pleasure to be here with you this morning.

I've been to Ellsworth many times, but a particularly fond memory was my joining in Ellsworth's 250th birthday celebration. I recall the enthusiasm, the hard work, and the widespread support that made it such a wonderful celebration of a rich history. That spirit defines this entire region, a spirit that the people of this region do not hold in reserve for special occasions every two and half centuries.

For many years, Ellsworth has been called "The Gateway to Acadia." Through your hard work and ingenuity, the Ellsworth area has become not just a gateway but an essential part of the Acadia experience.

In addition, the Ellsworth Incubator, the new Senior Center, and the Jackson Lab expansion are but a few of the ways people are working together to create new opportunities that go beyond our beautiful Acadia.

I thought I would spend some time today sharing with you some of my work as chairman of the Senate Special Committee on Aging. I sought this position because Maine is the oldest state in the nation by median age, and issues affecting older Americans were not getting sufficient attention.

The Committee has focused on preventing fraud and abuse against our seniors, strengthening financial security in retirement, and improving the quality of life through advances in innovation and research.

Recognizing that prescription drugs are vital to the health and well-being of many Americans, especially our nation's seniors, last fall the Committee began an in-depth investigation into the egregious and sudden spikes we are seeing in the prices of decades-old prescription medications.

Our investigation has focused on four companies that schemed to impose and protect enormous price hikes, and what policy changes are needed to respond to their actions.

Over the course of our investigation, the Committee has held three hearings, interviewed dozens of patients, doctors, and health care experts from around the country, and reviewed nearly a million pages of documents to better understand the causes and effects of these outrageous price hikes. What we have found has repercussions for the American public and for our health care system.

Two of the companies we examined – Turing Pharmaceuticals and Retrophin, Inc. – were headed by Martin Shkreli and operated more like hedge funds than traditional pharmaceutical

companies. You may recall reading about Mr. Shkreli as he has been arrested and charged for unrelated securities fraud.

We discovered that Mr. Shkreli's companies had a basic but effective plan to identify and capture prescription drugs they could then exploit. Here are the elements of the business model his companies were following in buying medications:

- First, they identified a sole source drug, which already has the field to itself and faces no competitor.
- Second, they make sure it's the "gold standard" for the condition it treats, so doctors can't prescribe a substitute treatment or won't feel comfortable doing so.
- Third, they selected drugs that serve a small patient population. Fewer patients means less scrutiny and less incentive for a competitor to enter the market.
- Fourth, they put the drug in a closed distribution system, or specialty pharmacy, which essentially preserves the firm's monopoly. This move helps keep generic competitors out of the market, as they can't get the supply required to conduct bioequivalence tests needed for FDA approval of a generic alternative.
- Fifth, they accomplished their ultimate goal. They jacked-up prices as high as possible, and watched the money roll in.

The decisions made by these companies did not play out in a vacuum. The price hikes had real implications for patients and providers. At one of our hearings, Shannon Weston of North Carolina testified about her family's experience. She and her husband were overjoyed when she gave birth to a beautiful baby girl last year, but their joy quickly turned to anxiety when they learned that their baby had a rare disease: congenital toxoplasmosis.

The good news was that a year's treatment with an effective drug called Daraprim, which had been on the market since 1953, would save their infant daughter from death or a lifetime of disability. The bad news? Daraprim had been acquired by Turing Pharmaceuticals, which had raised the price of this life-saving medicine from $13.50 per pill to an astounding $750 per pill. Instead of facing a cost of $6,500 for a year's treatment for their daughter, a cost that would be daunting enough, the Westons would now have to pay more than $360,000, an impossible amount that their insurer refused to cover.

Shannon explored taking a second mortgage on her home, cashing in her retirement account and going on TV to plead for help. Fortunately, a physician at the University of North Carolina at Chapel Hill connected her with its pharmacy program, which allows her to pay a highly subsidized cost of $218 a month for the desperately needed Daraprim. And today, her baby daughter is doing well.

The Committee also heard the sworn testimony of three Turing insiders – one who protested the unjustified price increase and lost his job as a result, and two who stayed and helped carry out the greedy scheme that caused hardship for patients and providers, prevented generic competitors from entering the market, and enriched the company.

Keep in mind that Turing had not invested a single penny in the research and clinical trials that led to the development of Daraprim. In fact, Turing did not even exist until 2014, more than 60 years after Daraprim first came onto the market.

In our most recent hearing, we examined another company: Valeant Pharmaceuticals, a multi-national company with approximately 22,000 employees that operates in more than 100 countries. Valeant is much larger and more established than either of the two companies once headed by Martin Shkreli. But like those two companies, Valeant also bought drugs that had been affordable and easy to get for decades, and then jacked up their prices. Also like Turing, Valeant didn't spend a penny to develop the drugs we investigated, and its manufacturing costs hadn't changed. In other words, there was no justification for the enormous price increases it charged for these purchased drugs.

At our hearing we heard from Berna Heyman, a retired college librarian from Virginia, who has Wilson's disease, an inherited disorder that prevents copper from being excreted from the body, causing dangerous accumulations. Untreated, it can lead to serious liver, brain, and eye problems, and even death. Treated, the individual can live a normal life.

There are, however, very few medicines that can treat Wilson's disease. The main drugs are Syprine and Cuprimine, and Valeant bought them both.

For years, Mrs. Heyman took Syprine, which worked well for her. Then Valeant purchased Syprine and hiked its price from $652 for a monthly supply to an outrageous $21,267. The company bought Cuprimine, too, and jacked up its price by nearly 6,000 percent. Suddenly, Mrs. Heyman could no longer afford the copay on the medicine that she needed to avoid the terrible consequences of Wilson's disease. After a frantic but unsuccessful search for financial assistance, she was ultimately forced to switch to an alternative that is not the preferred treatment for Wilson's disease.

Another witness at that hearing was the former CEO of Valeant. He said that he regretted his decision to increase prices on certain decades-old drugs after his company acquired them but offered no real justification for price hikes. The new CEO has reduced the prices of two cardiac drugs somewhat, and he has said that price decreases for the two Wilson's medications are also under consideration. Whether the price reductions will come anywhere close to undoing the unconscionable increases remains to be seen.

I should make clear that the pharmaceutical industry obviously plays a vital role in our health care system. Developing drugs is usually an enormously time-consuming, expensive, and uncertain process. It often takes more than a decade to bring a new drug from the laboratory to the market, and estimates of the average cost of doing so range from hundreds of millions of dollars to well over a billion dollars. Moreover, the chance a new drug will succeed is highly uncertain. If we want new medicines to reach consumers who need them, the companies that invest in the research and take the risks necessary to develop these drugs must see a fair return on their investment.

But the kind of price manipulation I have described is a market failure with real consequences. It has consequences for doctors who are treating individuals who need these drugs. It has consequences for our hospitals at a time when they are trying to lower health care costs, and they can't control the cost of drugs that their patients desperately need. And most of all, it has dire consequences for patients like the baby with toxoplasmosis and people like Mrs. Heyman with a rare disease.

This abusive pricing is also a failure of the processes we have in the federal government to try to incentivize lower-priced generics to come on the market and compete with such monopoly drugs, once their patents have expired.

To protect the public, Congress must act to address this price manipulation. We need policy reforms, such as the bipartisan legislation I have introduced with Senator Claire McCaskill, to fast-track the approval of certain generic drugs that could compete with decades-old monopoly drugs that are vulnerable to abusive pricing. Our investigation has exposed the problem; we must now work to get solutions so that patients can access the lifesaving medications they need.

Thank you, and I'll be happy to take your questions.