

Opening Statement
Senator Susan M. Collins
Special Committee on Aging
“Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines”
December 9, 2015

Good afternoon. Today is the first hearing in this Committee’s bipartisan investigation into the sudden and dramatic price increases charged by certain pharmaceutical companies for off-patent prescription drugs they acquired.

Prescription drugs are vital to the health and well-being of all Americans, especially our nation’s seniors, 90 percent of whom take at least one prescription drug in any given month. For many Americans, access to prescription drugs is not only critical to their quality of life, but can literally be a matter of life or death.

Developing these 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 upwards of \$5 billion.

Moreover, the chance a new drug will succeed is highly uncertain. Studies show for those drugs that do reach the clinical trials stage, just one in seven will ultimately receive FDA approval.

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.

At the same time, we cannot be blind to the cost of these drugs to individuals, health systems, and the federal government. Americans are expected to spend more than \$328 billion on prescription drugs this year alone. Of this amount, individuals will pay about \$50 billion out-of-pocket. The federal government will pick up another \$110 billion in payments through Medicare, Medicaid, Veterans Affairs, and other programs.

For many decades, federal policy has sought to strike the right balance between maintaining the incentives needed to promote innovation and the development of new drugs and keeping medicines affordable. One way we have done so is by granting pharmaceutical companies exclusive rights through our patent system to sell the prescription drugs they develop for approximately 20 years. When these patents expire, other companies can seek approval to enter the market to offer generic versions of these drugs. This increases competition and helps lower prices.

That balance we have struck never anticipated companies acquiring off-patent drugs and then jacking up their prices to enormous heights, and doing so, as one executive essentially put it, “because I can.” But that is exactly what we have seen in recent months.

Four companies in particular have come to our attention and are the focus of our investigation thus far: Turing Pharmaceuticals, Valeant Pharmaceuticals, Retrophin, Inc., and Rodelis Therapeutics. Each of these companies has hiked the price of off-patent drugs they recently acquired by twenty, thirty, or even forty times the prior price, at times putting these drugs out of reach for patients and the doctors who treat them.

Keep in mind that these companies did not bear the R&D costs of developing these drugs. In fact, some of these companies appear to do comparatively little or no R&D, or expensive clinical trials, for prescription medicines.

The information this committee has received in the initial phase of this investigation is striking. For example, doctors at the Cleveland Clinic have told us that price hikes on just two drugs supplied by Valeant – Isuprel and Nitropress - increased that health system's total drug costs by \$8.6 million.

Erin Fox, who will testify today, has seen a similar impact on the University of Utah Health System. As the director of the hospital's Drug Information Service, she has told us that these price increases have required her to literally put a critical drug under lock and key, pulling it from "crash carts" where it had long been available for emergency use.

In North Carolina, doctors for a child diagnosed with toxoplasmosis were unable to get Daraprim - the drug needed to treat that disease - because Turing Pharmaceuticals had hiked the price by more than 40 times its original cost, forcing the local pharmacy to drop it from its inventory. As a consequence, the child had to be treated with an alternative that had not been rigorously tested in children.

The Turing and Valeant price spikes have been egregious, but these are not the only two companies to acquire the rights to off-patent brand name drugs and then hike up the price. Rodelis did the same with a medicine that has been on the market since 1955 that is used to treat drug-resistant tuberculosis. And Retrophin did the same with a drug used to treat serious kidney disease.

What explains these dramatic price increases? One factor each of these drugs has in common is that they are needed by a relatively small number of people compared to so-called "blockbuster" drugs that are taken by millions of Americans. Another is that they have been off-patent for many years, yet there is no current generic competition, likely because of the relatively small number of patients who require these drugs.

This investigation is not about the legitimate incentives to create and market new drugs. After the patent on a prescription drug expires, however, our system relies upon competition to bring more affordable generics to the marketplace. But when competition breaks down - where there is a "market failure," as may be the case here - the discipline that keeps prices in check and protects consumers can disappear.

Let me close by noting that some of the companies that have been the focus of our investigation look more like hedge funds than they do pharmaceutical companies. As one industry expert I recently spoke with put it, "these companies are to ethical pharmaceutical companies as a loan shark is to a bank." One goal of our bipartisan investigation is to understand why such companies can impose egregious price increases on off-patent drugs they have acquired, and what policies we should consider to counter this disturbing practice.

I look forward to the statement of Ranking Member McCaskill and the testimony of our witnesses.