

**Opening Statement
Senator Susan M. Collins
Special Committee on Aging**

“Sudden Price Spikes in Decades-Old Drugs: Inside the Monopoly Business Model”

March 17, 2016

Good morning. Last fall, this Committee launched a bipartisan investigation into the sudden, enormous price increases on decades-old prescription drugs. Our focus today is on two companies in particular that operate more like hedge funds than they do traditional pharmaceutical companies -- Turing Pharmaceuticals and Retrophin, Inc. The Committee has investigated how these companies devised their business models to impose and protect egregious price hikes, and what policy changes are needed to respond to their actions.

These two hedge fund pharmaceuticals were both founded by Martin Shkreli: Retrophin in 2011 and Turing in 2014.

Our investigation has determined that these companies follow a business model with five key elements. I now submit, for the Record, Committee exhibits containing more than a thousand pages of documents that reveal the structure of this business model, which operates like this:

- First, the companies identify an older, brand name, sole-source drug. They choose a drug whose patents have long since expired, which already has the field to itself, and which faces no generic competitor;
- Second, they make sure that the drug is the “gold standard” for the condition it treats, so that health care providers can’t prescribe a substitute treatment or won’t feel comfortable in doing so;
- Third, they select a drug that serves 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 gives the companies a monopoly. This move is key because it keeps generic companies from competing in the market because they can’t get the supply required to conduct bioequivalence tests needed for FDA approval. As Martin Shkreli told potential investors in 2014, “We do not sell Retrophin products to generic companies.”
- Fifth, they accomplish their ultimate goal. Soon after Mr. Shkreli made that statement in reference to the drug Thiola, which is used to treat a rare kidney disease, that drug began generating revenue at a level 5,000 percent higher than it had produced for its previous owner.

In October of 2014, Mr. Shkreli left Retrophin to start Turing, bringing with him former Retrophin consultant Ron Tilles, who is now Turing's CEO and Chairman of the Board, Edwin Urrutia, now Turing's CFO, Michael Smith, now Turing's Senior Director of Business Development, and, most important, the business model I have described.

Applying this business model, they acquired a drug called "Daraprim," which is the gold standard medicine used to treat toxoplasmosis. Daraprim has been on the market since 1953, yet it has no generic competitor.

When they acquired Daraprim, it was selling for about \$13.50 per pill. Turing raised the price of this low profile but very important medicine to \$750 per pill, which amounted to \$75,000 per bottle.

Today, we will hear the sworn testimony of three company insiders -- one who protested the business model and lost his job because of it, and two who stayed and helped to carry out the greedy scheme that caused hardship for patients and providers, prevented generic competition, and enriched the companies.

These decisions made by these companies did not play out in a vacuum. We will hear from the mother of an infant diagnosed with congenital toxoplasmosis, who, as a result of Turing's actions, faced a price tag of \$28,000 a month for the medicine she needed to save her infant daughter from death or a lifetime of disability.

An infectious disease expert will also provide her perspective on the impact of this price manipulation scheme on real people who are struggling to get access to drugs they can't afford and desperately need.

Whether or not these companies' actions are legal, their behavior harms patients, represents a market failure, and is a call to action.

I now welcome the statement of our Ranking Member, Senator Claire McCaskill, who has done tremendous work on this important issue.

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